

US3522128 (Prod: Henry Ford Health System)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:32:11

All time stamps listed in this document are displayed in GMT

US3522128

Form: Participant Creation

Generated On: 26 Nov 2020 09:32:11

[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 09:32:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 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 09:32:11

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
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 09:32:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 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 09:32:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:32:11

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

Condition	PAST OF STROKE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐
	No ☒
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

Condition	HYPERPARATHYROIDISM
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

Condition	CHF
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

Condition	CAD
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

Condition	CKD STAGE 3
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

Condition	AFIB
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

Condition	CARDIOMYOPATHY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

Condition	GOUT (FLAIRS IN LEFT KNEE AND RIGHT ELBOW)
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	9:50 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 9:50
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	240 lb
BMI (<i>xxx.x</i>)	34.50842 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 09:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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 09:32:11

Occupational Risk

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

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 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 09:32:11

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 186311

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:11

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 09:32:11

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)	14 AUG 2020
Time of assessment (00:00-23:59)	9:50 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 9:50
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 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 09:32:11

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)	14 AUG 2020
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:56
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

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 09:32:11

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)	14 AUG 2020
What was the treatment time? (00:00-23:59)	10:26 (24 HR)
Treatment Date and Time (derived)	14 AUG 2020 10:26
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 09:32:11

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	14 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:15 (24 HR)
Collection date and time (derived)	14 AUG 2020 10:15

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:11

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:17	14 AUG 2020 10:17
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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 09:32:11

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

97.3 °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

14 AUG 2020 10:56

PC Open Date & Time

14 AUG 2020 10:46

PC Close Date & Time

14 AUG 2020 13:16

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

100.4 °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	14 AUG 2020 20:47
PC Open Date & Time	14 AUG 2020 14:11
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.6 °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

15 AUG 2020 22:37

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

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

99.9 °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

16 AUG 2020 20:40

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

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**

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

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**

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

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

97.9 °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

19 AUG 2020 23:54

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 21:51

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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

14 AUG 2020 10:59

PC Open Date & Time

14 AUG 2020 10:46

PC Close Date & Time

14 AUG 2020 13:16

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

14 AUG 2020 20:49

PC Open Date & Time

14 AUG 2020 14:11

PC Close Date & Time

15 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 22:38

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 20:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

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)**

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)**

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

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

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)**

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)**

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

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

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

19 AUG 2020 23:55

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

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

20 AUG 2020 21:51

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 11:00
PC Open Date & Time	14 AUG 2020 10:46
PC Close Date & Time	14 AUG 2020 13:16

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 20:50
PC Open Date & Time	14 AUG 2020 14:11
PC Close Date & Time	15 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

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 ☒

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

Yes ☐	
PC Time stamp	15 AUG 2020 22:40
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

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 ☒

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

Yes ☐	
PC Time stamp	16 AUG 2020 20:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

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 ☒

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

Yes ☐	
PC Time stamp	19 AUG 2020 23:56
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

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 ☒

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

Yes ☐	
PC Time stamp	20 AUG 2020 21:52
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3522128

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	22 AUG 2020 09:52
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3522128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT HAD FATIGUE, MILD
FEVER, AND HEADACHE AFTER
INJECTION. NO COVID
EXPOSURE, CHANGES IN
HEALTH, OR MEDS.

US3522128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

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

NOT DONE

If Contact Not Made, please provide Comments

US3522128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

US3522128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	12:59 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:59
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:04
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3522128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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 SEP 2020

What was the treatment time? (00:00-23:59) 13:34 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 13:34

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

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:20 (24 HR)
Collection date and time (derived)	11 SEP 2020 13:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:11

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:25	11 SEP 2020 13:25
Nasopharyngeal Swab 2	No		

US3522128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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**

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 11 SEP 2020 13:54

PC Close Date & Time 11 SEP 2020 16:24

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

97.2 °F

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

Yes ☐
No ☒

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

PC Time Stamp	11 SEP 2020 21:34
PC Open Date & Time	11 SEP 2020 17:19
PC Close Date & Time	12 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

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 ☒

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 06:50

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

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

95.3 °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

15 SEP 2020 08:19

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

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

97.5 °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

16 SEP 2020 10:56

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

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**

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

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**

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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 SEP 2020 14:04

PC Open Date & Time

11 SEP 2020 13:54

PC Close Date & Time

11 SEP 2020 16:24

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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 SEP 2020 21:35

PC Open Date & Time

11 SEP 2020 17:19

PC Close Date & Time

12 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 21:53

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 06:50

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 08:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 10:57

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

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)**

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)**

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

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

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 ☐

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

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)**

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

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 13:54

PC Close Date & Time

11 SEP 2020 16:24

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:36
PC Open Date & Time	11 SEP 2020 17:19
PC Close Date & Time	12 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

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 ☒

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

Yes ☐	
PC Time stamp	12 SEP 2020 21:53
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

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 ☒

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

Yes ☐	
PC Time stamp	14 SEP 2020 06:51
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

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 ☒

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

Yes ☐	
PC Time stamp	15 SEP 2020 08:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

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 ☒

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

Yes ☐	
PC Time stamp	16 SEP 2020 10:57
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

CURRENTLY AT UOFM ED
WITH HIGH HR AND LOW BP.
HAD PREVIOUS HEART
PROBLEM BUT THIS NOT AFIB
AGAIN. NO MED CHANGES
CURRENTLY. NO AES, COVID
EXPOSURE.

US3522128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

HOSPITAL VISIT 9/25-9/27 FOR
A-FIB EPISODE. NOW HAS
SCHEDULED ABLATION 10/6.
GIVEN MEDS BUT UNABLE TO
RECALL NAME; WILL BRING TO
NEXT APPOINTMENT. DENIES
COVID EXPOSURE.
DOCUMENTED FULLY IN
SOURCE

US3522128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

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.

US3522128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3522128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

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12 NOV 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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14 JAN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

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21 JAN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

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Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

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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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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03 MAR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

Date and time of submission

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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

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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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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07 APR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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17 APR 2022 00:01

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21 APR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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09 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

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19 JUN 2022 00:01

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23 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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30 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

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17 JUL 2022 00:01

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21 JUL 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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28 JUL 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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04 AUG 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3522128

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:32:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522128

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:32:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

AEID	
Adverse event	EPISODE OF AFIB
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)	27 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	27 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

337 of 2037

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	14 AUG 2020
Start time (00:00-23:59)	20:47 (24 HR)
AE start date and time (derived)	14 AUG 2020 20:47
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	15 AUG 2020
End time (00:00-23:59)	23:59 (24 HR)
AE End Date and Time (derived)	15 AUG 2020 23:59
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

339 of 2037

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

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)	

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

AEID	USA-US131-2020-MRNA-1273-P30 1000008
Adverse event	ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE
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)	25 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)	27 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	True
Hospital Admission Date (dd MMM yyyy)	25 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	27 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

VISITED HOSPITAL LAST WEEK
R/T INCREASED HR AND
DECREASED BP. DIAGNOSED
WITH A-FLUTTER. HOSPITAL
STAY AT UOFM OVER
WEEKEND FRI-SUN; 9/25-9/27.
NOW HAS PLANNED ABLATION
ON 10/6/2020. STATES HE WAS
GIVEN MEDICATION TO TAKE
FOR HEART RHYTHM CONTROL
: METROPROLOL, DIGOXIN AND
CHANGE IN HIS FUROSEMIDE
MEDICATION.

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

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

AEID	USA-US131-2020-MRNA-1273-P30 1000008
Adverse event	MULTIFOCAL PNEUMONIA IN BOTH LUNGS
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)	8 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)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	12 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

ON THURSDAY 10/8 NOTICED
WORSENING SHORTNESS OF
BREATH, DIZZINESS,
HEMOPTYSIS, AND A FEVER
MEASURED TO 99.4F.
PRESENTED TO ED LATER IN
THE DAY WHERE HE
DEMONSTRATED A NEW
OXYGEN REQUIREMENT
(BASELINE ON ROOM AIR)

BRIEF HOSPITAL COURSE
(INCLUDING TREATMENT
RENDERED AND RESPONSE TO
TREATMENT):

(b) (6) WAS ADMITTED
TO MM FOR MULTIFOCAL
HCAP ON 10/8. IN ED, PATIENT
EXPERIENCED WORSENING
HYPOXIA ON CPAP WITH 10L
NC. HE WAS TRANSFERRED TO
EC3 AT MIDNIGHT FOR
WORSENING CLINICAL STATUS
AND WAS PLACED ON HHFNC
DUE TO PERSISTENT HYPOXIA.
HE WAS SUBSEQUENTLY
WEANED TO NC AROUND 8AM
ON 10/9. CT SCAN IN THE ED
WAS CONSISTENT WITH
MULTIFOCAL PNEUMONIA. HIS
INR WAS ELEVATED TO 3.7 ON
ADMISSION, WHICH WAS
THOUGH TO BE THE SOURCE
OF HIS HEMOPTYSIS. HE
APPEARED EUVOLEMIC ON
EXAMINATION, BUT WAS
NOTED TO BE IN AFIB WHILE IN

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

THE ED. THERE WERE NO
APPARENT SIGNS OF
CONGESTIVE HEART FAILURE.
HIS BNP WAS 295. BLOOD AND
SPUTUM CULTURES WERE
OBTAINED, AND THE PATIENT
WAS THEN TREATED WITH
VANCOMYCIN AND
PIPERACILLIN/TAZOBACTAM.
THE FOLLOWING DAY, THE
PATIENT STATED THAT HE
WAS MUCH IMPROVED. HE
WAS SUBSEQUENTLY WEANED
FROM NASAL CANULA ON
10/10. REPARATORY CULTURES
SHOWED ONLY NORMAL ORAL
FLORA. BLOOD CULTURES
WERE NGTD THROUGH 10/11.
ON 10/11, THE PATIENT WAS
TRANSITIONED TO ORAL
LEVOFLOXACIN AND FLAGYL.
AND HE CONTINUED TO
IMPROVE FROM A
RESPIRATORY STANDPOINT
RESOLVING LATER THAT DAY.
MOVED FROM WARFARIN TO
ELIQUIS. 10/12 THE PATIENT
WAS DISCHARGED IN HIS
NORMAL STATE OF HEALTH.
LUNGS WERE CLEAR TO
AUSCULTATION BILATERALLY,
AND THE PATIENT HAD NO
FURTHER EPISODES OF
HEMOPTYSIS. HE REMAINED
AFEBRILE. HE CONTINUED
ANTIBIOTIC THERAPY FOR A
TOTAL OF 7 DAYS.

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

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

AEID	
Adverse event	GOUT FLAIR
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 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)	11 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 ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	WHILE IN HOSPITAL FOR UNRELATED CONCERNS, HAD A GOUT FLAIRUP IN THE USUAL LOCATION OF THE LEFT KNEE AND RIGHT ELBOW WHICH WAS TREATED BY ANAKINRA AND PREDNISONE. FELT BETTER THE FOLLOWING DAY. WILL FOLLOW UP WITH PCP
Serious Adverse Event Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:32:11

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	WARFARIN
Prophylaxis	Yes ☐ No ☒
Indication	AFIB
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 ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

	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)		
Start date completely unknown		True
Ongoing?		Yes ☐
		No ☒
If not Ongoing, End date (dd MMM yyyy)		11 OCT 2020
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ☒
Indication	TYPE TWO DIABETES
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 ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

	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)		
Start date completely unknown		True
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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	NEUROPOTHY
Dose per administration	300
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

	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)		
Start date completely unknown		True
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 ☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
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 ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

	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)		
Start date completely unknown		True
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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	METOPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION / AFIB
Dose per administration	25
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

	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)		
Start date completely unknown		True
Ongoing?		Yes ☐
		No ☒
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2017
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 ☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

	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)		
Start date completely unknown		True
Ongoing?		Yes ☐
		No ☒
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	DILTIAZAM
Prophylaxis	Yes ☐ No ☒
Indication	AFIB
Dose per administration	240
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

	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)		
Start date completely unknown		True
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 ☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	METROPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION/AFIB
Dose per administration	25
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 ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	DIGOXIN
Prophylaxis	Yes ☐ No ☒
Indication	ATRIAL FIBRILLATION
Dose per administration	125
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

	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)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		27 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	DIGOXIN
Prophylaxis	Yes ☐ No ☒
Indication	ATRIAL FLUTTER WITH RVR
Dose per administration	250
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 25 SEP 2020	
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	VANCOMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	MULTIFOCAL PNEUMONIA IN BOTH LUNGS
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 ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	PIPERACILLIN/TAZOBACTAM
Prophylaxis	Yes ☐ No ☒
Indication	MULTIFOCAL PNEUMONIA IN BOTH LUNGS
Dose per administration	4.5G
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 8 HOURS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

	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)	8 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		11 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	VANCOMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	MULTIFOCAL PNEUMONIA IN BOTH LUNGS
Dose per administration	1250
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 ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

	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)	09 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		11 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	LEVOFLOXACIN
Prophylaxis	Yes ☐ No ☒
Indication	MULTIFOCAL PNEUMONIA IN BOTH LUNGS
Dose per administration	750
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 ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

	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)	11 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	FLAGYL
Prophylaxis	Yes ☐ No ☒
Indication	MULTIFOCAL PNEUMONIA IN BOTH LUNGS
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 8 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

	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)	11 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ☒
Indication	ATRIAL FIBRILLATION
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 12 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

Name of Medication	ANAKINRA
Prophylaxis	Yes ☐ No ☒
Indication	GOUT FLAIR
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 ☐

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:32:11

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:32:11

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
29 AUG 2020	CARDIOVERSION	Medical History	
06 OCT 2020	ELECTIVE ABLATION IN HEART FOR AFIB	Medical History	

US3522128

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:32:11

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

US3522128

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:32:11

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 ☐

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:11

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:11

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/OCT/2020 15:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:11

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/OCT/2020 16:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:11

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☒ No ☐
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/OCT/2020 14:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3522128 (Prod: Henry Ford Health System)

US3522128

Form: Participant Creation

Generated On: 26 Nov 2020 09:32:11

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3522128'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Aug 2020 13:44:16

US3522128

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:46:35

US3522128

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 13:44:17

US3522128

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:46:35

US3522128

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Aug 2020 13:46:35

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 13:44:18

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Age](#)

Audit	User	Time (GMT)
User entered '70'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '70'	System	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[White](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Black](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:11

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 13:44:17

US3522128

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 13:47:27

US3522128

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:27

US3522128

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:32:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:15

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:03:27
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Updated. on metformin' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:47:35
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:41:15
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 13:56:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 13:56:23
Data point term sent to Coder	System	14 Aug 2020 13:55:11
User entered 'TYPE 2 DIABETEs' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:50
User entered 'tYPE 2 diabeteSe'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:49:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:49:52
Data point term sent to Coder	System	14 Aug 2020 14:10:38
User entered 'PAST OF STROKE'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of PAST OF STROKE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 11:57:23
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	05 Oct 2020 17:48:02
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of PAST OF STROKE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:47:55
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	05 Oct 2020 17:47:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:47:41
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of PAST OF STROKE may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:39:52
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:48:02
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Parathyroid gland disorders, HLT: Hyperparathyroid disorders, PT: Hyperparathyroidism, LLT: Hyperparathyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:12:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:12:19
Data point term sent to Coder	System	14 Aug 2020 14:11:40
User entered 'HYPERPARATHYROIDISM'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 14:12:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 14:12:19
Data point term sent to Coder	System	14 Aug 2020 14:11:40
User entered 'CHF'	Kristin Eis (b) (4)	14 Aug 2020 14:11:20
	(b) (4)	

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	14 Aug 2020 14:13:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:13:22
Data point term sent to Coder	System	14 Aug 2020 14:12:42
User entered 'CAD'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please review and confirm if this condition can interfere with subject's ability to participate in the trial.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:10:34
Query 'Per MM: Please review and confirm if this condition can interfere with subject's ability to participate in the trial.' answered with 'No, it will not interfere' (Site from DM).	mayur ramesh (b) (4)	08 Sep 2020 12:43:25
User opened query 'Per MM: Please review and confirm if this condition can interfere with subject's ability to participate in the trial.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 15:23:33
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:20:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:20:18
Data point term sent to Coder	System	14 Aug 2020 14:12:41
User entered 'CKD stage 3'	Kristin Eis (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

[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)	14 Aug 2020 14:13:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 14:13:22
Data point term sent to Coder	System	14 Aug 2020 14:12:42
User entered 'Hypertension'	Kristin Eis (b) (4)	14 Aug 2020 14:12:36
	(b) (4)	

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: AFib - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 14:14:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 14:14:25
Data point term sent to Coder	System	14 Aug 2020 14:13:45
User entered 'AFIB'	Kristin Eis (b) (4)	14 Aug 2020 14:13:00
	(b) (4)	

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 14:14:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 14:14:25
Data point term sent to Coder	System	14 Aug 2020 14:13:45
User entered 'Cardiomyopathy'	Kristin Eis (b) (4)	14 Aug 2020 14:13:38
	(b) (4)	

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 17:47:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 17:47:28
Data point term sent to Coder	System	05 Oct 2020 17:46:30
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	05 Oct 2020 17:46:24
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	05 Oct 2020 17:46:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:46:24
User entered '1'	(b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout flare - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 00:47:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 00:47:24
Data point term sent to Coder	System	22 Oct 2020 18:24:16
User entered 'Gout (Flairs in Left Knee and Right Elbow)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '9:50'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 9:50'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '70' in	Kristin Eis (b) (4)	14 Aug 2020 13:49:14
DataPoint set to visible.	(b) (4) System	14 Aug 2020 13:47:27

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '240' lb	Kristin Eis (b) (4)	14 Aug 2020 13:49:14
DataPoint set to visible.	(b) (4) System	14 Aug 2020 13:47:27

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '34.50842'	System	16 Sep 2020 23:56:51
User entered '34.5'	System	14 Aug 2020 13:49:14
DataPoint set to visible.	System	14 Aug 2020 13:47:27

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Aug 2020 13:49:14
DataPoint set to visible.	System	14 Aug 2020 13:47:27

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 15:08:35
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'Done' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 12:45:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 12:45:22
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 06:07:12
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 14:18:50
Query 'Data is required. Please provide.' answered by System data change (Site from System).		17 Aug 2020 14:18:50
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:18:50
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 13:49:14
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:39

US3522128

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

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)	13 Sep 2020 17:49:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 16:58:39
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:47:39

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:11

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:33

US3522128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:33

US3522128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:33

US3522128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	14 Aug 2020 13:49:33

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Aug 2020 13:44:24

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:11

[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 04:27:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:27:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 13:44:24
User entered '186311' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Aug 2020 13:44:24

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Aug 2020 13:44:24

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 13:52:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 13:52:50
User entered 'No (N)' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:52:50
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 13:51:19
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:51:19

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 13:52:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 13:52:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:52:50
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 13:51:19
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:51:19

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:51:19

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:51:19

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:11

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:51:19

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '68' in	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:11

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '240' lb reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:39
User entered '140' lb	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '68' in	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:11

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '240' lb reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:39
User entered '140' lb	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 13:51:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 13:51:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:51:01
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 13:49:55
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '9:50' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 9:50'	System	14 Aug 2020 13:51:01
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4)	01 Oct 2020 19:58:36
User entered 'infrared' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 13:51:01
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '18' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 13:51:01
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '102' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 13:51:01
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 09:04:43
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4)	17 Sep 2020 13:28:43
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:56:51
User entered '59' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 13:51:01
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '68' in	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:11

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '240' lb reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:51:39
User entered '140' lb	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 19:11:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 19:11:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 13:49:55
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 15:59:21
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).		14 Aug 2020 19:11:21
User entered '10:56' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:56'	System	14 Aug 2020 19:11:21
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Sep 2020 13:30:30
User entered 'Infared' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 19:11:21
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 19:11:21
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '113' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 19:11:21
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 19:11:21
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 19:11:21
User entered empty.	System	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:49
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:04

US3522128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	17 Aug 2020 14:19:49
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:04

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Aug 2020 14:29:19
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	14 Aug 2020 14:29:19
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Aug 2020 13:53:57
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '10:26' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 14:29:19
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:26'	System	14 Aug 2020 14:29:19
User entered empty.	System	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 13:54:07
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:11

US3522128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:11

US3522128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '10:15'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:11

US3522128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:15'	System	14 Aug 2020 14:35:11

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '10:17'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:17'	System	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:19

US3522128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 13:49:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:52:53', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0a2bf38a-ae1f-4252-a60e-047f8026af18'	System	14 Aug 2020 14:56:27
User entered 'Yes (Y)'	System	14 Aug 2020 14:56:27

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:53:02', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0a2bf38a-ae1f-4252-a60e-047f8026af18'	System	14 Aug 2020 14:56:27
User entered '97.3'	System	14 Aug 2020 14:56:27

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:53:13', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0a2bf38a-ae1f-4252-a60e-047f8026af18'	System	14 Aug 2020 14:56:27
User entered 'No (N)'	System	14 Aug 2020 14:56:27

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:56:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0a2bf38a-ae1f-4252-a60e-047f8026af18'	System	14 Aug 2020 14:56:27
User entered '14 Aug 2020 10:56'	System	14 Aug 2020 14:56:27

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:46'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 13:16'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:46:19', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c335b7d5-428d-4152-9705-12d945b89eb9'	System	15 Aug 2020 00:47:20
User entered 'Yes (Y)'	System	15 Aug 2020 00:47:20

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:46:42', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c335b7d5-428d-4152-9705-12d945b89eb9' User entered '100.4'	System	15 Aug 2020 00:47:20

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:47:02', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c335b7d5-428d-4152-9705-12d945b89eb9'	System	15 Aug 2020 00:47:20
User entered 'No (N)'	System	15 Aug 2020 00:47:20

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:47:16', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c335b7d5-428d-4152-9705-12d945b89eb9'	System	15 Aug 2020 00:47:20
User entered '14 Aug 2020 20:47'	System	15 Aug 2020 00:47:20

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:11'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 2'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:37:11', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6bad894-cba0-43f7-849b-d89c9d66eaff'	System	16 Aug 2020 02:37:32
User entered 'Yes (Y)'	System	16 Aug 2020 02:37:32

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:37:18', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6bad894-cba0-43f7-849b-d89c9d66eaff'	System	16 Aug 2020 02:37:32
User entered '99.6'	System	16 Aug 2020 02:37:32

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:37:23', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6bad894-cba0-43f7-849b-d89c9d66eaff'	System	16 Aug 2020 02:37:32
User entered 'No (N)'	System	16 Aug 2020 02:37:32

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:37:30', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6bad894-cba0-43f7-849b-d89c9d66eaff'	System	16 Aug 2020 02:37:32
User entered '15 Aug 2020 22:37'	System	16 Aug 2020 02:37:32

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 3'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:39:50', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '060eba42-ad95-42f7-9098-30eba5c80711'	System	17 Aug 2020 00:40:08
User entered 'Yes (Y)'	System	17 Aug 2020 00:40:08

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:39:57', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '060eba42-ad95-42f7-9098-30eba5c80711'	System	17 Aug 2020 00:40:08
User entered '99.9'	System	17 Aug 2020 00:40:08

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:40:01', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '060eba42-ad95-42f7-9098-30eba5c80711'	System	17 Aug 2020 00:40:08
User entered 'No (N)'	System	17 Aug 2020 00:40:08

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:40:06', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '060eba42-ad95-42f7-9098-30eba5c80711'	System	17 Aug 2020 00:40:08
User entered '16 Aug 2020 20:40'	System	17 Aug 2020 00:40:08

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 4'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 5'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 6'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:51:51', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '5deab05c-41bf-478a-a54c-bedb6198c501'	System	20 Aug 2020 03:54:42
User entered 'Yes (Y)'	System	20 Aug 2020 03:54:42

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:52:15', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '5deab05c-41bf-478a-a54c-bedb6198c501'	System	20 Aug 2020 03:54:42
User entered '97.9'	System	20 Aug 2020 03:54:42

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:52:20', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '5deab05c-41bf-478a-a54c-bedb6198c501'	System	20 Aug 2020 03:54:42
User entered 'No (N)'	System	20 Aug 2020 03:54:42

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:54:38', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '5deab05c-41bf-478a-a54c-bedb6198c501'	System	20 Aug 2020 03:54:42
User entered '19 Aug 2020 23:54'	System	20 Aug 2020 03:54:42

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 7'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:50:47', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ebf142bd-91ed-4ffe-a339-79865aa3015e'	System	21 Aug 2020 01:51:11
User entered 'Yes (Y)'	System	21 Aug 2020 01:51:11

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:50:55', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ebf142bd-91ed-4ffe-a339-79865aa3015e'	System	21 Aug 2020 01:51:11
User entered '98.1'	System	21 Aug 2020 01:51:11

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:01', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ebf142bd-91ed-4ffe-a339-79865aa3015e'	System	21 Aug 2020 01:51:11
User entered 'No (N)'	System	21 Aug 2020 01:51:11

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:09', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ebf142bd-91ed-4ffe-a339-79865aa3015e'	System	21 Aug 2020 01:51:11
User entered '20 Aug 2020 21:51'	System	21 Aug 2020 01:51:11

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:58:21', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b34dcc8c-483f-4eaf-9946-3c3a5435590d'	System	14 Aug 2020 14:59:27
User entered 'None (1)'	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:58:58', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b34dcc8c-483f-4eaf-9946-3c3a5435590d'	System	14 Aug 2020 14:59:27
User entered 'No (N)'	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:59:02', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b34dcc8c-483f-4eaf-9946-3c3a5435590d'	System	14 Aug 2020 14:59:27
User entered 'No (N)'	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:59:10', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b34dcc8c-483f-4eaf-9946-3c3a5435590d'	System	14 Aug 2020 14:59:27
User entered 'None (1)'	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:59:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b34dcc8c-483f-4eaf-9946-3c3a5435590d'	System	14 Aug 2020 14:59:27
User entered '14 Aug 2020 10:59'	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:46'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 13:16'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:47:44', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '05ed4457-94e8-4238-8a73-788735fdf51f'	System	15 Aug 2020 00:49:18
User entered 'None (1)'	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:48:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '05ed4457-94e8-4238-8a73-788735fdf51f'	System	15 Aug 2020 00:49:18
User entered 'No (N)'	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:48:41', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '05ed4457-94e8-4238-8a73-788735fdf51f'	System	15 Aug 2020 00:49:18
User entered 'No (N)'	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:49:07', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '05ed4457-94e8-4238-8a73-788735fdf51f'	System	15 Aug 2020 00:49:18
User entered 'None (1)'	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:49:17', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '05ed4457-94e8-4238-8a73-788735fdf51f'	System	15 Aug 2020 00:49:18
User entered '14 Aug 2020 20:49'	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:11'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 2'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:37:55', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '69f51b99-1d10-4ec7-b758-26d59d890955'	System	16 Aug 2020 02:38:54
User entered 'None (1)'	System	16 Aug 2020 02:38:54

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:38:04', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '69f51b99-1d10-4ec7-b758-26d59d890955'	System	16 Aug 2020 02:38:54
User entered 'No (N)'	System	16 Aug 2020 02:38:54

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:38:27', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '69f51b99-1d10-4ec7-b758-26d59d890955'	System	16 Aug 2020 02:38:54
User entered 'No (N)'	System	16 Aug 2020 02:38:54

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:38:45', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '69f51b99-1d10-4ec7-b758-26d59d890955'	System	16 Aug 2020 02:38:54
User entered 'None (1)'	System	16 Aug 2020 02:38:54

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:38:52', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '69f51b99-1d10-4ec7-b758-26d59d890955'	System	16 Aug 2020 02:38:54
User entered '15 Aug 2020 22:38'	System	16 Aug 2020 02:38:54

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 3'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:40:23', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '4dd6f976-821d-4b5c-b2f0-2490ad18aa24'	System	17 Aug 2020 00:41:37
User entered 'None (1)'	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:40:28', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '4dd6f976-821d-4b5c-b2f0-2490ad18aa24'	System	17 Aug 2020 00:41:37
User entered 'No (N)'	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:40:31', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '4dd6f976-821d-4b5c-b2f0-2490ad18aa24'	System	17 Aug 2020 00:41:37
User entered 'No (N)'	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:41:07', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '4dd6f976-821d-4b5c-b2f0-2490ad18aa24'	System	17 Aug 2020 00:41:37
User entered 'None (1)'	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:41:34', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '4dd6f976-821d-4b5c-b2f0-2490ad18aa24'	System	17 Aug 2020 00:41:37
User entered '16 Aug 2020 20:41'	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 4'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 5'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 6'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:54:45', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6c888ef-a3cb-45c9-9a09-fdd718749586'	System	20 Aug 2020 03:55:19
User entered 'None (1)'	System	20 Aug 2020 03:55:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:54:54', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6c888ef-a3cb-45c9-9a09-fdd718749586'	System	20 Aug 2020 03:55:19
User entered 'No (N)'	System	20 Aug 2020 03:55:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:55:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6c888ef-a3cb-45c9-9a09-fdd718749586'	System	20 Aug 2020 03:55:19
User entered 'No (N)'	System	20 Aug 2020 03:55:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:55:06', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6c888ef-a3cb-45c9-9a09-fdd718749586'	System	20 Aug 2020 03:55:19
User entered 'None (1)'	System	20 Aug 2020 03:55:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:55:15', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f6c888ef-a3cb-45c9-9a09-fdd718749586'	System	20 Aug 2020 03:55:19
User entered '19 Aug 2020 23:55'	System	20 Aug 2020 03:55:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 7'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:16', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6726da46-b8e1-433d-8bfd-e3b898589f6c'	System	21 Aug 2020 01:51:34
User entered 'None (1)'	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:20', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6726da46-b8e1-433d-8bfd-e3b898589f6c'	System	21 Aug 2020 01:51:34
User entered 'No (N)'	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:23', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6726da46-b8e1-433d-8bfd-e3b898589f6c'	System	21 Aug 2020 01:51:34
User entered 'No (N)'	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:26', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6726da46-b8e1-433d-8bfd-e3b898589f6c'	System	21 Aug 2020 01:51:34
User entered 'None (1)'	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:29', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6726da46-b8e1-433d-8bfd-e3b898589f6c'	System	21 Aug 2020 01:51:34
User entered '20 Aug 2020 21:51'	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:59:35', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9c833fa4-c89b-496e-9d61-5f07310051db'	System	14 Aug 2020 15:00:28
User entered 'None (0)'	System	14 Aug 2020 15:00:28

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:59:40', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9c833fa4-c89b-496e-9d61-5f07310051db' User entered 'None (0)'	System	14 Aug 2020 15:00:28
	System	14 Aug 2020 15:00:28

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:59:45', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9c833fa4-c89b-496e-9d61-5f07310051db' User entered 'None (0)'	System	14 Aug 2020 15:00:28
	System	14 Aug 2020 15:00:28

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:59:48', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9c833fa4-c89b-496e-9d61-5f07310051db'	System	14 Aug 2020 15:00:28
User entered 'None (0)'	System	14 Aug 2020 15:00:28

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T10:59:55', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9c833fa4-c89b-496e-9d61-5f07310051db'	System	14 Aug 2020 15:00:28
User entered 'None (0)'	System	14 Aug 2020 15:00:28

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T11:00:01', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9c833fa4-c89b-496e-9d61-5f07310051db' User entered 'None (0)'	System	14 Aug 2020 15:00:28
	System	14 Aug 2020 15:00:28

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T11:00:10', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9c833fa4-c89b-496e-9d61-5f07310051db'	System	14 Aug 2020 15:00:28
User entered 'No (N)'	System	14 Aug 2020 15:00:28

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T11:00:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9c833fa4-c89b-496e-9d61-5f07310051db'	System	14 Aug 2020 15:00:28
User entered '14 Aug 2020 11:00'	System	14 Aug 2020 15:00:28

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:46'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 13:16'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
Comment added 'Addressed with patient. Not bed bound for day, level two AE'.	(b) (4), (b) (6)	04 Sep 2020 19:52:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:49:26', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'bfc7ab00-e0d3-4048-a1b3-02b175528cc0'	System	15 Aug 2020 00:51:00
User entered 'None (0)'	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
Comment added 'Addressed with patient. Not level 3 AE. Pt not bedbound all day. level 2'.	(b) (4), (b) (6)	04 Sep 2020 19:53:39
Comment added 'Level 2 AE not 3'.	(b) (4), (b) (6)	04 Sep 2020 19:52:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:49:53', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'bfc7ab00-e0d3-4048-a1b3-02b175528cc0'	System	15 Aug 2020 00:51:00
User entered 'Significant; prevents daily activity (3)'	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:50:04', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'bfc7ab00-e0d3-4048-a1b3-02b175528cc0'	System	15 Aug 2020 00:51:00
User entered 'None (0)'	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:50:09', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'bfc7ab00-e0d3-4048-a1b3-02b175528cc0'	System	15 Aug 2020 00:51:00
User entered 'None (0)'	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:50:17', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'bfc7ab00-e0d3-4048-a1b3-02b175528cc0'	System	15 Aug 2020 00:51:00
User entered 'None (0)'	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:50:42', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'bfc7ab00-e0d3-4048-a1b3-02b175528cc0'	System	15 Aug 2020 00:51:00
User entered 'Some interference with activity not requiring medical attention (2)'	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:50:52', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'bfc7ab00-e0d3-4048-a1b3-02b175528cc0'	System	15 Aug 2020 00:51:00
User entered 'No (N)'	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-14T20:50:59', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'bfc7ab00-e0d3-4048-a1b3-02b175528cc0'	System	15 Aug 2020 00:51:00
User entered '14 Aug 2020 20:50'	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 14:11'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 2'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:39:10', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '28975730-8c20-4cc9-a2ad-f15753c7b76b'	System	16 Aug 2020 02:40:44
User entered 'None (0)'	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
Comment added 'Comment added 'Addressed with patient. Not level 3 AE. Pt not bedbound all day. level 2'.	(b) (4), (b) (6)	04 Sep 2020 19:54:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:39:35', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '28975730-8c20-4cc9-a2ad-f15753c7b76b'	System	16 Aug 2020 02:40:44
User entered 'Significant; prevents daily activity (3)'	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:39:41', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '28975730-8c20-4cc9-a2ad-f15753c7b76b'	System	16 Aug 2020 02:40:44
User entered 'None (0)'	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:39:45', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '28975730-8c20-4cc9-a2ad-f15753c7b76b'	System	16 Aug 2020 02:40:44
User entered 'None (0)'	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:39:50', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '28975730-8c20-4cc9-a2ad-f15753c7b76b'	System	16 Aug 2020 02:40:44
User entered 'None (0)'	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:40:24', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '28975730-8c20-4cc9-a2ad-f15753c7b76b'	System	16 Aug 2020 02:40:44
User entered 'Some interference with activity not requiring medical attention (2)'	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:40:36', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '28975730-8c20-4cc9-a2ad-f15753c7b76b'	System	16 Aug 2020 02:40:44
User entered 'No (N)'	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-15T22:40:41', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '28975730-8c20-4cc9-a2ad-f15753c7b76b'	System	16 Aug 2020 02:40:44
User entered '15 Aug 2020 22:40'	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 3'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:41:48', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c5aa1094-05f3-4408-91fc-73e6b88c9d67'	System	17 Aug 2020 00:42:39
User entered 'None (0)'	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:41:58', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c5aa1094-05f3-4408-91fc-73e6b88c9d67'	System	17 Aug 2020 00:42:39
User entered 'Some interference with activity (2)'	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:42:06', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c5aa1094-05f3-4408-91fc-73e6b88c9d67'	System	17 Aug 2020 00:42:39
User entered 'None (0)'	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:42:13', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c5aa1094-05f3-4408-91fc-73e6b88c9d67'	System	17 Aug 2020 00:42:39
User entered 'None (0)'	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:42:18', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c5aa1094-05f3-4408-91fc-73e6b88c9d67'	System	17 Aug 2020 00:42:39
User entered 'None (0)'	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:42:24', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c5aa1094-05f3-4408-91fc-73e6b88c9d67'	System	17 Aug 2020 00:42:39
User entered 'None (0)'	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:42:30', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c5aa1094-05f3-4408-91fc-73e6b88c9d67'	System	17 Aug 2020 00:42:39
User entered 'No (N)'	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-16T20:42:38', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'c5aa1094-05f3-4408-91fc-73e6b88c9d67'	System	17 Aug 2020 00:42:39
User entered '16 Aug 2020 20:42'	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 4'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 5'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 6'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:55:29', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6478b161-2467-45f3-b1cc-2c75b09d367a'	System	20 Aug 2020 03:56:40
User entered 'None (0)'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:55:49', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6478b161-2467-45f3-b1cc-2c75b09d367a'	System	20 Aug 2020 03:56:40
User entered 'No interference with activity (1)'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:56:03', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6478b161-2467-45f3-b1cc-2c75b09d367a'	System	20 Aug 2020 03:56:40
User entered 'None (0)'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:56:07', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6478b161-2467-45f3-b1cc-2c75b09d367a'	System	20 Aug 2020 03:56:40
User entered 'None (0)'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:56:16', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6478b161-2467-45f3-b1cc-2c75b09d367a'	System	20 Aug 2020 03:56:40
User entered 'None (0)'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:56:22', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6478b161-2467-45f3-b1cc-2c75b09d367a'	System	20 Aug 2020 03:56:40
User entered 'None (0)'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:56:29', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6478b161-2467-45f3-b1cc-2c75b09d367a'	System	20 Aug 2020 03:56:40
User entered 'No (N)'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-19T23:56:34', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '6478b161-2467-45f3-b1cc-2c75b09d367a'	System	20 Aug 2020 03:56:40
User entered '19 Aug 2020 23:56'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 7'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:36', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9fc4c095-90d4-4f4b-9c00-cc3f15679226'	System	21 Aug 2020 01:52:04
User entered 'None (0)'	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:41', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9fc4c095-90d4-4f4b-9c00-cc3f15679226'	System	21 Aug 2020 01:52:04
User entered 'None (0)'	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:44', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9fc4c095-90d4-4f4b-9c00-cc3f15679226'	System	21 Aug 2020 01:52:04
User entered 'None (0)'	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:47', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9fc4c095-90d4-4f4b-9c00-cc3f15679226'	System	21 Aug 2020 01:52:04
User entered 'None (0)'	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:50', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9fc4c095-90d4-4f4b-9c00-cc3f15679226'	System	21 Aug 2020 01:52:04
User entered 'None (0)'	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:53', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9fc4c095-90d4-4f4b-9c00-cc3f15679226'	System	21 Aug 2020 01:52:04
User entered 'None (0)'	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:51:58', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9fc4c095-90d4-4f4b-9c00-cc3f15679226'	System	21 Aug 2020 01:52:04
User entered 'No (N)'	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-20T21:52:02', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '9fc4c095-90d4-4f4b-9c00-cc3f15679226'	System	21 Aug 2020 01:52:04
User entered '20 Aug 2020 21:52'	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 03:56:40
User entered 'Day 8'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-22T09:52:19', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '3a22dc0d-6ef8-45e7-8bd1-31710e376829'	System	22 Aug 2020 13:52:26
User entered 'No (N)'	System	22 Aug 2020 13:52:26

US3522128

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-08-22T09:52:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '3a22dc0d-6ef8-45e7-8bd1-31710e376829'	System	22 Aug 2020 13:52:26
User entered '22 Aug 2020 09:52'	System	22 Aug 2020 13:52:26

US3522128

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 03:56:40

US3522128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:35:47

US3522128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:35:47

US3522128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:35:47

US3522128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Patient had fatigue, mild fever, and headache after injection. No covid exposure, changes in health, or meds.' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 19:46:00
User entered 'Pt is doing good, no adverse events'	Jo-Ann Rammal (b) (4)	21 Aug 2020 19:35:47

US3522128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:35:53

US3522128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 19:35:53

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 19:41:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 19:41:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 19:41:11
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 19:41:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:41:05

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:41:05

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:41:05

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'not done'	(b) (4), (b) (6)	04 Sep 2020 19:41:05

US3522128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:41:19

US3522128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 19:41:19

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:41:52

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 19:41:52

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 19:41:52

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4), (b) (6)	04 Sep 2020 19:41:52

US3522128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:41:56

US3522128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 19:41:56

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 16:58:39

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 16:58:39

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 16:58:39

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	11 Sep 2020 16:58:39

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '12:59'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:59'	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '100'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 09:16:50
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jelena Verkler (b) (4) (b) (4)	17 Sep 2020 16:33:35
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:56:51
User entered '57'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 18:08:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 18:08:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 17:00:31
User entered empty.	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '14:04' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 14:04'	System	11 Sep 2020 18:08:42
User entered empty.	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '97.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 18:08:42
User entered empty.	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 18:08:42
User entered empty.	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '96' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 18:08:42
User entered empty.	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 09:16:56
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Jelena Verkler (b) (4) (b) (4)	17 Sep 2020 16:33:50
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:56:51
User entered '58' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 18:08:42
User entered empty.	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:36

US3522128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	11 Sep 2020 17:00:45
User entered '11 Sep 2020' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:45
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	11 Sep 2020 17:00:36
User entered empty.	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:00:36

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Sep 2020 17:39:40
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	11 Sep 2020 17:39:40
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Sep 2020 17:01:20
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '13:34' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:39:40
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:01:20
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:34'	System	11 Sep 2020 17:39:40
User entered empty.	System	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:39:06

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:39:06

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '13:20'	(b) (4), (b) (6)	11 Sep 2020 17:39:06

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:20'	System	11 Sep 2020 17:39:06

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '13:25'	(b) (4), (b) (6)	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:25'	System	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:11

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:01:25

US3522128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:01:25

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:54'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:24'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:34:14', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '54058c22-9905-46cb-bd0a-e995cfa52ec0'	System	12 Sep 2020 01:34:40
User entered 'Yes (Y)'	System	12 Sep 2020 01:34:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:34:22', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '54058c22-9905-46cb-bd0a-e995cfa52ec0'	System	12 Sep 2020 01:34:40
User entered '97.2'	System	12 Sep 2020 01:34:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:34:29', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '54058c22-9905-46cb-bd0a-e995cfa52ec0'	System	12 Sep 2020 01:34:40
User entered 'No (N)'	System	12 Sep 2020 01:34:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:34:38', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '54058c22-9905-46cb-bd0a-e995cfa52ec0'	System	12 Sep 2020 01:34:40
User entered '11 Sep 2020 21:34'	System	12 Sep 2020 01:34:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:19'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 2'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:51:54', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0629a0ff-8b98-4c6e-bf7e-3cb5579f66e0'	System	13 Sep 2020 01:52:17
User entered 'Yes (Y)'	System	13 Sep 2020 01:52:17

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:52:01', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0629a0ff-8b98-4c6e-bf7e-3cb5579f66e0'	System	13 Sep 2020 01:52:17
User entered '97.6'	System	13 Sep 2020 01:52:17

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:52:06', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0629a0ff-8b98-4c6e-bf7e-3cb5579f66e0'	System	13 Sep 2020 01:52:17
User entered 'No (N)'	System	13 Sep 2020 01:52:17

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:52:14', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0629a0ff-8b98-4c6e-bf7e-3cb5579f66e0'	System	13 Sep 2020 01:52:17
User entered '12 Sep 2020 21:52'	System	13 Sep 2020 01:52:17

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 3'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:49:48', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ca120798-84c1-433c-8d3e-114f44635e6f'	System	14 Sep 2020 10:50:07
User entered 'No (N)'	System	14 Sep 2020 10:50:07

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:49:54', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ca120798-84c1-433c-8d3e-114f44635e6f'	System	14 Sep 2020 10:50:07
User entered 'No (N)'	System	14 Sep 2020 10:50:07

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:50:05', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ca120798-84c1-433c-8d3e-114f44635e6f' User entered '14 Sep 2020 06:50'	System	14 Sep 2020 10:50:07
	System	14 Sep 2020 10:50:07

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 4'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:19:27', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '99f108c4-2dac-4d86-a11b-fd2d21d1da84'	System	15 Sep 2020 12:19:56
User entered 'Yes (Y)'	System	15 Sep 2020 12:19:56

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:19:40', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '99f108c4-2dac-4d86-a11b-fd2d21d1da84'	System	15 Sep 2020 12:19:56
User entered '95.3'	System	15 Sep 2020 12:19:56

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:19:46', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '99f108c4-2dac-4d86-a11b-fd2d21d1da84'	System	15 Sep 2020 12:19:56
User entered 'No (N)'	System	15 Sep 2020 12:19:56

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:19:51', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '99f108c4-2dac-4d86-a11b-fd2d21d1da84'	System	15 Sep 2020 12:19:56
User entered '15 Sep 2020 08:19'	System	15 Sep 2020 12:19:56

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 5'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:56:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '877bcf4a-c79a-42fe-8ad5-d6d913da95ae'	System	16 Sep 2020 14:56:43
User entered 'Yes (Y)'	System	16 Sep 2020 14:56:43

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:56:32', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '877bcf4a-c79a-42fe-8ad5-d6d913da95ae'	System	16 Sep 2020 14:56:43
User entered '97.5'	System	16 Sep 2020 14:56:43

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:56:37', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '877bcf4a-c79a-42fe-8ad5-d6d913da95ae'	System	16 Sep 2020 14:56:43
User entered 'No (N)'	System	16 Sep 2020 14:56:43

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:56:41', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '877bcf4a-c79a-42fe-8ad5-d6d913da95ae' User entered '16 Sep 2020 10:56'	System	16 Sep 2020 14:56:43
	System	16 Sep 2020 14:56:43

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 6'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 7'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T14:04:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e64904f1-7eab-4892-8219-46dc5aea6f'	System	11 Sep 2020 18:04:48
User entered 'None (1)'	System	11 Sep 2020 18:04:48

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T14:04:06', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e64904f1-7eab-4892-8219-46dc5aea6f'	System	11 Sep 2020 18:04:48
User entered 'No (N)'	System	11 Sep 2020 18:04:48

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T14:04:10', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e64904f1-7eab-4892-8219-46dc5aea6f'	System	11 Sep 2020 18:04:48
User entered 'No (N)'	System	11 Sep 2020 18:04:48

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T14:04:17', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e64904f1-7eab-4892-8219-46dc5aea6f'	System	11 Sep 2020 18:04:48
User entered 'None (1)'	System	11 Sep 2020 18:04:48

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T14:04:38', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e64904f1-7eab-4892-8219-46dc5aea6f'	System	11 Sep 2020 18:04:48
User entered '11 Sep 2020 14:04'	System	11 Sep 2020 18:04:48

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:54'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:24'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:34:50', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ddfefdef-5656-4d6b-a06a-54e1b88b8685'	System	12 Sep 2020 01:35:46
User entered 'None (1)'	System	12 Sep 2020 01:35:46

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:34:53', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ddfefdef-5656-4d6b-a06a-54e1b88b8685'	System	12 Sep 2020 01:35:46
User entered 'No (N)'	System	12 Sep 2020 01:35:46

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:34:56', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ddfefdef-5656-4d6b-a06a-54e1b88b8685'	System	12 Sep 2020 01:35:46
User entered 'No (N)'	System	12 Sep 2020 01:35:46

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:35:34', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ddfefdef-5656-4d6b-a06a-54e1b88b8685'	System	12 Sep 2020 01:35:46
User entered 'None (1)'	System	12 Sep 2020 01:35:46

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:35:41', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ddfefdef-5656-4d6b-a06a-54e1b88b8685'	System	12 Sep 2020 01:35:46
User entered '11 Sep 2020 21:35'	System	12 Sep 2020 01:35:46

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:19'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 2'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:41', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '663d33ac-71ea-4fa5-8745-f7194ea62e8c' User entered 'None (1)'	System	13 Sep 2020 01:54:01
	System	13 Sep 2020 01:54:01

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:45', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '663d33ac-71ea-4fa5-8745-f7194ea62e8c'	System	13 Sep 2020 01:54:01
User entered 'No (N)'	System	13 Sep 2020 01:54:01

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:50', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '663d33ac-71ea-4fa5-8745-f7194ea62e8c' User entered 'No (N)'	System	13 Sep 2020 01:54:01

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:54', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '663d33ac-71ea-4fa5-8745-f7194ea62e8c'	System	13 Sep 2020 01:54:01
User entered 'None (1)'	System	13 Sep 2020 01:54:01

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:59', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '663d33ac-71ea-4fa5-8745-f7194ea62e8c' User entered '12 Sep 2020 21:53'	System	13 Sep 2020 01:54:01

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 3'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:50:34', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2eb8854a-e6ea-4634-8b52-5b2ab04880f0'	System	14 Sep 2020 10:51:02
User entered 'None (1)'	System	14 Sep 2020 10:51:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:50:40', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2eb8854a-e6ea-4634-8b52-5b2ab04880f0'	System	14 Sep 2020 10:51:02
User entered 'No (N)'	System	14 Sep 2020 10:51:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:50:45', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2eb8854a-e6ea-4634-8b52-5b2ab04880f0'	System	14 Sep 2020 10:51:02
User entered 'No (N)'	System	14 Sep 2020 10:51:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:50:51', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2eb8854a-e6ea-4634-8b52-5b2ab04880f0' User entered 'None (1)'	System	14 Sep 2020 10:51:02
	System	14 Sep 2020 10:51:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:50:58', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2eb8854a-e6ea-4634-8b52-5b2ab04880f0' User entered '14 Sep 2020 06:50'	System	14 Sep 2020 10:51:02
	System	14 Sep 2020 10:51:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 4'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:19:58', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd0a90aae-a9e4-492e-92cf-c2235cb2b2d8'	System	15 Sep 2020 12:20:17
User entered 'None (1)'	System	15 Sep 2020 12:20:17

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:03', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd0a90aae-a9e4-492e-92cf-c2235cb2b2d8'	System	15 Sep 2020 12:20:17
User entered 'No (N)'	System	15 Sep 2020 12:20:17

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:06', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd0a90aae-a9e4-492e-92cf-c2235cb2b2d8'	System	15 Sep 2020 12:20:17
User entered 'No (N)'	System	15 Sep 2020 12:20:17

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:10', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd0a90aae-a9e4-492e-92cf-c2235cb2b2d8'	System	15 Sep 2020 12:20:17
User entered 'None (1)'	System	15 Sep 2020 12:20:17

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:13', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd0a90aae-a9e4-492e-92cf-c2235cb2b2d8' User entered '15 Sep 2020 08:20'	System	15 Sep 2020 12:20:17
	System	15 Sep 2020 12:20:17

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 5'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

[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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:56:48', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ce308958-9c9a-407a-ba84-001e8677f493'	System	16 Sep 2020 14:57:02
User entered 'None (1)'	System	16 Sep 2020 14:57:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:56:51', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ce308958-9c9a-407a-ba84-001e8677f493'	System	16 Sep 2020 14:57:02
User entered 'No (N)'	System	16 Sep 2020 14:57:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:56:55', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ce308958-9c9a-407a-ba84-001e8677f493'	System	16 Sep 2020 14:57:02
User entered 'No (N)'	System	16 Sep 2020 14:57:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:56:57', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ce308958-9c9a-407a-ba84-001e8677f493'	System	16 Sep 2020 14:57:02
User entered 'None (1)'	System	16 Sep 2020 14:57:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:01', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'ce308958-9c9a-407a-ba84-001e8677f493'	System	16 Sep 2020 14:57:02
User entered '16 Sep 2020 10:57'	System	16 Sep 2020 14:57:02

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 6'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 7'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:54'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:24'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:35:53', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '94fcd8a9-9323-4f5e-a96d-4e2572bb5af0'	System	12 Sep 2020 01:36:43
User entered 'None (0)'	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:36:04', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '94fcd8a9-9323-4f5e-a96d-4e2572bb5af0'	System	12 Sep 2020 01:36:43
User entered 'Some interference with activity (2)'	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:36:09', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '94fcd8a9-9323-4f5e-a96d-4e2572bb5af0'	System	12 Sep 2020 01:36:43
User entered 'None (0)'	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:36:13', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '94fcd8a9-9323-4f5e-a96d-4e2572bb5af0'	System	12 Sep 2020 01:36:43
User entered 'None (0)'	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:36:18', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '94fcd8a9-9323-4f5e-a96d-4e2572bb5af0'	System	12 Sep 2020 01:36:43
User entered 'None (0)'	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:36:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '94fcd8a9-9323-4f5e-a96d-4e2572bb5af0'	System	12 Sep 2020 01:36:43
User entered 'None (0)'	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:36:32', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '94fcd8a9-9323-4f5e-a96d-4e2572bb5af0'	System	12 Sep 2020 01:36:43
User entered 'No (N)'	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-11T21:36:40', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '94fcd8a9-9323-4f5e-a96d-4e2572bb5af0'	System	12 Sep 2020 01:36:43
User entered '11 Sep 2020 21:36'	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:19'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 2'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:52:40', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2adc71a3-e3e4-439f-b8b0-ebf1ebf69872'	System	13 Sep 2020 01:53:36
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:52:49', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2adc71a3-e3e4-439f-b8b0-ebf1ebf69872'	System	13 Sep 2020 01:53:36
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:52:54', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2adc71a3-e3e4-439f-b8b0-ebf1ebf69872'	System	13 Sep 2020 01:53:36
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:52:58', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2adc71a3-e3e4-439f-b8b0-ebf1ebf69872'	System	13 Sep 2020 01:53:36
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:05', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2adc71a3-e3e4-439f-b8b0-ebf1ebf69872'	System	13 Sep 2020 01:53:36
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:15', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2adc71a3-e3e4-439f-b8b0-ebf1ebf69872'	System	13 Sep 2020 01:53:36
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:22', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2adc71a3-e3e4-439f-b8b0-ebf1ebf69872'	System	13 Sep 2020 01:53:36
User entered 'No (N)'	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-12T21:53:32', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '2adc71a3-e3e4-439f-b8b0-ebf1ebf69872'	System	13 Sep 2020 01:53:36
User entered '12 Sep 2020 21:53'	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 3'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:51:11', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd7498a47-2aa0-41d5-a35c-9aa7b6e4643e'	System	14 Sep 2020 10:52:00
User entered 'None (0)'	System	14 Sep 2020 10:52:00

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:51:18', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd7498a47-2aa0-41d5-a35c-9aa7b6e4643e'	System	14 Sep 2020 10:52:00
User entered 'None (0)'	System	14 Sep 2020 10:52:00

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:51:22', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd7498a47-2aa0-41d5-a35c-9aa7b6e4643e'	System	14 Sep 2020 10:52:00
User entered 'None (0)'	System	14 Sep 2020 10:52:00

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:51:32', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd7498a47-2aa0-41d5-a35c-9aa7b6e4643e' User entered 'None (0)'	System	14 Sep 2020 10:52:00
	System	14 Sep 2020 10:52:00

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:51:35', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd7498a47-2aa0-41d5-a35c-9aa7b6e4643e'	System	14 Sep 2020 10:52:00
User entered 'None (0)'	System	14 Sep 2020 10:52:00

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:51:42', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd7498a47-2aa0-41d5-a35c-9aa7b6e4643e'	System	14 Sep 2020 10:52:00
User entered 'None (0)'	System	14 Sep 2020 10:52:00

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:51:50', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd7498a47-2aa0-41d5-a35c-9aa7b6e4643e'	System	14 Sep 2020 10:52:00
User entered 'No (N)'	System	14 Sep 2020 10:52:00

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-14T06:51:57', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd7498a47-2aa0-41d5-a35c-9aa7b6e4643e' User entered '14 Sep 2020 06:51'	System	14 Sep 2020 10:52:00
	System	14 Sep 2020 10:52:00

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 4'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:22', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f5643e31-174f-405d-bd96-7c95d64bc3cb'	System	15 Sep 2020 12:21:04
User entered 'None (0)'	System	15 Sep 2020 12:21:04

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:29', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f5643e31-174f-405d-bd96-7c95d64bc3cb' User entered 'None (0)'	System	15 Sep 2020 12:21:04
	System	15 Sep 2020 12:21:04

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:37', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f5643e31-174f-405d-bd96-7c95d64bc3cb' User entered 'None (0)'	System	15 Sep 2020 12:21:04
	System	15 Sep 2020 12:21:04

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:40', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f5643e31-174f-405d-bd96-7c95d64bc3cb' User entered 'None (0)'	System	15 Sep 2020 12:21:04
	System	15 Sep 2020 12:21:04

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:43', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f5643e31-174f-405d-bd96-7c95d64bc3cb'	System	15 Sep 2020 12:21:04
User entered 'None (0)'	System	15 Sep 2020 12:21:04

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:46', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f5643e31-174f-405d-bd96-7c95d64bc3cb' User entered 'None (0)'	System	15 Sep 2020 12:21:04
	System	15 Sep 2020 12:21:04

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:20:52', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f5643e31-174f-405d-bd96-7c95d64bc3cb'	System	15 Sep 2020 12:21:04
User entered 'No (N)'	System	15 Sep 2020 12:21:04

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-15T08:21:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f5643e31-174f-405d-bd96-7c95d64bc3cb' User entered '15 Sep 2020 08:21'	System	15 Sep 2020 12:21:04
	System	15 Sep 2020 12:21:04

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 5'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:07', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f3982ed2-12be-4ab4-b4ea-3fd5a4abec52'	System	16 Sep 2020 14:57:30
User entered 'None (0)'	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:09', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f3982ed2-12be-4ab4-b4ea-3fd5a4abec52'	System	16 Sep 2020 14:57:30
User entered 'None (0)'	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:11', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f3982ed2-12be-4ab4-b4ea-3fd5a4abec52'	System	16 Sep 2020 14:57:30
User entered 'None (0)'	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:13', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f3982ed2-12be-4ab4-b4ea-3fd5a4abec52'	System	16 Sep 2020 14:57:30
User entered 'None (0)'	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:15', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f3982ed2-12be-4ab4-b4ea-3fd5a4abec52'	System	16 Sep 2020 14:57:30
User entered 'None (0)'	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:17', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f3982ed2-12be-4ab4-b4ea-3fd5a4abec52'	System	16 Sep 2020 14:57:30
User entered 'None (0)'	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

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 (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:22', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f3982ed2-12be-4ab4-b4ea-3fd5a4abec52'	System	16 Sep 2020 14:57:30
User entered 'No (N)'	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D167C375-ECFE-465E-B636-965EBBE3BCBF)', Time: '2020-09-16T10:57:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'f3982ed2-12be-4ab4-b4ea-3fd5a4abec52'	System	16 Sep 2020 14:57:30
User entered '16 Sep 2020 10:57'	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 6'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 17:39:40
User entered 'Day 7'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:39:40

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:39:40

US3522128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 15:09:47

US3522128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 15:09:47

US3522128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 15:09:47

US3522128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 15:09:47

US3522128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 15:09:56

US3522128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 15:09:56

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:19:37

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:19:37

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 17:19:37

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Currently at UofM ED with high HR and low BP. Had previous heart problem but this not AFib again. No med changes currently. No AEs, COVID exposure.'	(b) (4), (b) (6)	25 Sep 2020 17:19:37

US3522128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:19:45

US3522128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:19:45

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 15:26:08

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 15:26:08

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 15:26:08

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Hospital visit 9/25-9/27 for a-fib episode. Now has scheduled ablation 10/6. Given meds but unable to recall name; will bring to next appointment. Denies covid exposure. Documented fully in source' reason for change: New Information	(b) (4), (b) (6)	02 Oct 2020 15:37:23
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 15:26:08

US3522128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 15:37:27

US3522128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 15:37:27

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:08:47

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:08:47
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:08:47

US3522128

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:32:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:37
User entered 'Yes (Y)'	Tyler Prentiss (b) (4)	28 Aug 2020 17:33:31
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:15:53
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'To our knowledge not a worsening. Participant reported having events of Afib but it is not a constant.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 13:54:26
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:25:27
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 23:59:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 23:59:45
Data point term sent to Coder	System	28 Aug 2020 17:40:09
User entered 'Episode of Afib'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'Yes (Y)'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'No (N)'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'No (N)'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
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 16:11:22
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	11 Sep 2020 17:01:20
User entered '27 Aug 2020'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Aug 2020 17:56:27
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 17:56:27
User entered '17:00' reason for change: Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 17:56:11
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Aug 2020 17:39:45
User entered '00:00'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:56:27
User entered '27 Aug 2020 17:00'	System	28 Aug 2020 17:56:11
User entered '27 Aug 2020 00:00'	System	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'No (N)'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Aug 2020 17:56:11
User entered '27 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 17:56:11
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Aug 2020 17:39:45
User entered empty.	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	28 Aug 2020 17:56:27
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 17:56:27
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	28 Aug 2020 17:56:11
User entered '20:00' reason for change: Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 17:56:11
User entered empty.	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Aug 2020 17:56:27
User entered '27 Aug 2020 20:00'	System	28 Aug 2020 17:56:11
User entered empty.	System	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 17:56:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 17:56:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 17:56:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Aug 2020 17:39:45
User entered empty.	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'No (N)'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'Not Related (NOT RELATED)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'Not Related (NOT RELATED)'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'None (NONE)'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		28 Aug 2020 17:56:11
User entered '0' reason for change: Data Entry Error Sharon Mathys	(b) (4)	28 Aug 2020 17:56:11
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	28 Aug 2020 17:39:45
User entered '1'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '1'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	28 Aug 2020 17:57:21
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	28 Aug 2020 17:56:11
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	28 Aug 2020 17:56:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	28 Aug 2020 17:56:11
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	28 Aug 2020 17:39:45
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	28 Aug 2020 17:57:21
User entered 'Patient is feeling better today. Continues to take concomitant medications Warfarin, diltiazam and metoprolol for this condition.'	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4)	28 Aug 2020 17:39:45
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:51:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 19:51:48
Data point term sent to Coder	System	04 Sep 2020 19:50:23
User entered 'Headache'	(b) (4), (b) (6) (b) (4)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:16:11
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' answered with 'changed to unsolicited' (Site from DM).	Sharon Mathys (b) (4)	01 Oct 2020 15:07:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 15:07:02
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:26:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

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 16:11:22
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	11 Sep 2020 17:01:20
User entered '14 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '20:47'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 20:47'	System	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '23:59'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 23:59'	System	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Sep 2020 19:49:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 19:49:40
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Sep 2020 19:49:35
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:33
User entered 'USA-US131-2020-mRNA-1273-P301000008'	System	02 Oct 2020 16:58:21
User entered 'New'	(b) (4), (b) (6)	02 Oct 2020 16:58:21

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:26:08
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter with rapid ventricular response - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:37:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 17:37:42
Data point term sent to Coder	System	22 Oct 2020 17:36:37
User entered 'ATRIAL Flutter WITH RAPID VENTRICULAR RESPONSE' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:35:43
Data point term sent to Coder	System	22 Oct 2020 17:35:36
User entered 'ATRIAL FIBRILLATION with rapid ventricular response' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:34:51
Data point term sent to Coder	System	22 Oct 2020 17:34:35
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:34:17
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:34:17
User entered 'Atrial FIBrillation EPISODE' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:34:17
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:01:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:01:39
Data point term sent to Coder	System	02 Oct 2020 15:35:48
User entered 'A fib episode'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '25 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:26:12
DataPoint Un-verified.	Sharon Mathys (b) (4)	11 Oct 2020 01:36:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	11 Oct 2020 01:36:41
DataPoint Verified.	Sharon Mathys (b) (4)	08 Oct 2020 20:04:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:26:14
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	11 Oct 2020 01:37:13
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	11 Oct 2020 01:37:13
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	11 Oct 2020 01:36:41
DataPoint Un-verified.	Sharon Mathys (b) (4)	11 Oct 2020 01:36:41
User entered '27 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	11 Oct 2020 01:36:41
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:58:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:05:04
User entered empty.	System	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '25 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '27 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:54:04
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Con procedures for cardioversion and elective ablation both recorded with dates in concomitant procedures ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:19:20
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:02:00
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:26:19
DataPoint Un-verified.	Sharon Mathys (b) (4)	22 Oct 2020 17:37:04
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	22 Oct 2020 17:37:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:26:22
DataPoint Un-verified.	Sharon Mathys (b) (4)	11 Oct 2020 01:37:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Sharon Mathys (b) (4)	11 Oct 2020 01:37:13
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:26:38
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 15:15:15
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' answered with 'This has been done.' (Site from Safety).	Sharon Mathys (b) (4)	27 Oct 2020 15:41:21
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:22:33
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:22:02
User entered 'VISITED HOSPITAL LAST WEEK R/T INCREASED HR AND DECREASED BP. DIAGNOSED WITH A-FLUTTER. HOSPITAL STAY AT UOFM OVER WEEKEND FRI-SUN; 9/25-9/27. NOW HAS PLANNED ABLATION ON 10/6/2020. STATES HE WAS GIVEN MEDICATION TO TAKE FOR HEART RHYTHM CONTROL : Metoprolol, Digoxin and change in his furosemide medication.' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 19:27:37

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medications: New digoxin, Modified Metoprolol and Furosemide dosages. No surgical treatment done at this time' (Site from Safety).	Sharon Mathys (b) (4)	22 Oct 2020 17:57:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.:' answered with 'Not enough room in box to paste labs. EKG 9/25: A flutter with RVR	Sharon Mathys (b) (4)	22 Oct 2020 17:56:10
CXR 9/25: 1. Left atrial appendage clip. 2. Mild elevation of the left hemidiaphragm with slight interval increase. Mild left basilar atelectasis. No pneumothorax or pleural effusion. Normal cardiomediastinal silhouette. ' (Site from Safety).		
DataPoint Un-verified.	Sharon Mathys (b) (4)	22 Oct 2020 17:54:50
User entered 'VISITED HOSPITAL LAST WEEK R/T INCREASED HR AND DECREASED BP. DIAGNOSED WITH A-Flutter. HOSPITAL STAY AT UOFM OVER WEEKEND FRI-SUN; 9/25-9/27. NOW HAS PLANNED ABLATION ON 10/6/2020. STATES HE WAS GIVEN MEDICATION TO TAKE FOR HEART RHYTHM CONTROL BUT DOES NOT RECALL NAME OR DOSE AMOUNT. TOLD TO BRING INFORMATION WITH HIM TO NEXT IN PERSON APPOINTMENT OR CALL WITH INFO WHEN HE HAS THE CHANCE. DENIES COVID EXPOSURE OR OTHER CHANGES IN HEALTH STATUS' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:54:50

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342. ' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:08:56
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:06:01
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable:.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:05:15
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'Visited hospital last week r/t increased HR and decreased BP. Diagnosed with A-fib. Hospital stay at UofM over weekend Fri-Sun; 9/25-9/27. Now has planned ablation on 10/6/2020. States he was given medication to take for heart rhythm control but does not recall name or dose amount. Told to bring information with him to next in person appointment or call with info when he has the chance. Denies covid exposure or other changes in health status'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[AEID](#)

Audit	User	Time (GMT)
User closed query 'Please advise if this is related to AE log line # 5 for "ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE". These events have 2 different start dates and per source these are unrelated. Kindly advise.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:01:39
Query 'Please advise if this is related to AE log line # 5 for "ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE". These events have 2 different start dates and per source these are unrelated. Kindly advise.' answered with 'It is unrelated. I do not know who to notify to change the AEID. This was not made by anyone at HFHS' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	10 Nov 2020 19:10:03
User opened query 'Please advise if this is related to AE log line # 5 for "ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE". These events have 2 different start dates and per source these are unrelated. Kindly advise.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 18:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 18:30:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:26:47
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:52:33
User entered 'USA-US131-2020-mRNA-1273-P301000008'	(b) (4), (b) (6)	12 Oct 2020 15:52:29

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:35
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 23:31:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 23:31:29
Data point term sent to Coder	System	22 Oct 2020 18:00:31
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:00:24
User entered 'Multifocal Pneumonia in both lungs' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:00:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Pulmonary oedemas, PT: Pulmonary oedema, LLT: Pulmonary edema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 05:18:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 05:18:18
Data point term sent to Coder	System	11 Oct 2020 02:08:32
User entered 'PULMONARY EDEMA in both lungs' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:08:23
Data point term sent to Coder	System	11 Oct 2020 02:07:32
User entered 'Pulmonary Edema'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:37
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:39
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:41
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:42
User entered '8 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:44
User entered empty.	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:46
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Oct 2020 14:47:33
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:49
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	20 Oct 2020 14:47:33
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	20 Oct 2020 14:47:33
User entered '12 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Oct 2020 14:47:33
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	20 Oct 2020 14:46:23
User entered empty.	Sharon Mathys (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:53
User entered empty.	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:55
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:13:57
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:01
User entered '0'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:36
User entered '0'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 06:26:16
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 'updated as information came in' (Site from System).	Sharon Mathys (b) (4)	20 Oct 2020 14:46:11
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	11 Oct 2020 02:07:17
User entered '1'	Sharon Mathys (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:42
User entered '8 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:44
User entered '12 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Oct 2020 14:46:23
User entered empty.	Sharon Mathys (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:50
User entered empty.	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:57
User entered '0'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:58
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:14:59
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:08
User entered '0'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:12
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:36:24
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Per narrative associated with entry, medications given during hospital stay have been entered into concomitant medications tab. Vancomycin, Piperacillin/Tazobactam, Levofloxacin, Flagyl, Warfarin, and Eliquis all accounted for in ConMeds' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:26:23
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:02:41
User entered '1'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:15
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:02:18
User entered '1'	Sharon Mathys (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	20 Oct 2020 14:46:23
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:19
User entered empty.	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:24
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 15:15:28
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' answered with 'This has been done.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 15:41:30
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:23:14
User closed query 'PV Query: Please provide start dates to all concomitant medications and medical history.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:23:09
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:22:59
Query 'PV Query: Please provide start dates to all concomitant medications and medical history.' answered with 'Please clarify, for historical medications start date was not known and not communicated.. Start dates provided (and stop) for medications altered or administered during admission.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:47:29
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medications given presented in eCRF' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:46:41

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'On Thursday 10/8 noticed worsening shortness of breath, dizziness, hemoptysis, and a fever measured to 99.4F. Presented to ED later in the day where he demonstrated a new oxygen requirement (baseline on room air) Brief Hospital Course (including treatment rendered and response to treatment): (b) (6) was admitted to MM for multifocal HCAP on 10/8. In ED, patient experienced worsening hypoxia on CPAP with 10L NC. He was transferred to EC3 at midnight for worsening clinical status and was placed on HHFNC due to persistent hypoxia. He was subsequently weaned to NC around 8am on 10/9. CT scan in the ED was consistent with multifocal pneumonia. His INR was elevated to 3.7 on admission, which was thought to be the source of his hemoptysis. He appeared euvolemic on examination, but was noted to be in afib while in the ED. There were no apparent signs of congestive heart failure. His BNP was 295. Blood and sputum cultures were obtained, and the patient was then treated with vancomycin and piperacillin/tazobactam. The following day, the patient stated that he was much improved. He was subsequently weaned from nasal canula on 10/10. Reparatory cultures showed only normal oral flora. Blood cultures were NGTD through 10/11. On 10/11, the patient was transitioned to oral levofloxacin and flagyl. And He continued to improve from a respiratory standpoint resolving later that day. Moved from warfarin to eliquis. 10/12 the patient was discharged in his normal state of health. Lungs were clear to auscultation bilaterally, and the patient had no further episodes of hemoptysis. He remained afebrile. He continued antibiotic therapy for a total of 7 days.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:45:10

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.:' answered with 'PROCEDURE: CT CHEST NON CONTRAST - CHEST PROTOCOL 10/8/2020 (modified for space) CLINICAL INDICATION: Acute resp illness, > 40 years old COMPARISON: 10/2/2020, TECHNIQUE: Helical CT was performed of the chest (lung apices to bases) without intravenous contrast. Images were reconstructed at 1.25 mm slice thickness every 0.625 mm. MIP and coronal & sagittal MPR images were generated and reviewed. (DFOV = 40 cm) FINDINGS: Lungs/pleura: There are multifocal patchy mixed ground glass and airspace opacities throughout the lungs in the upper lobes, lower lobes and to a lesser extent in the middle lobe. Trace bilateral effusions. ' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:05:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.:' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:12:41
User opened query 'PV Query: Please provide start dates to all concomitant medications and medical history.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:11:56
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:10:42
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 16:10:00

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WENT TO HOSPITAL ON 10/6 FOR AN ELECTIVE PROCEDURE TO TREAT AFIB IN HEART. ENDED UP RETURNING 2 DAYS LATER WITH SEEMING PULMONARY EDEMA AND WAS ADMITTED. COVID-19 TEST TAKEN AND WAS NEGATIVE. STILL IN HOSPITAL BUT ON FLOOR NOT ICU. MORE DETAILS TO COME AS OF 10 OCT 2020. STAFF FOUND OUT THROUGH A SCHEDULING CALL ABOUT THE HOSPITALIZATION ON 09 OCT 2020. FOUND OUT MORE INFORMATION ON 10 OCT 2020. WAITING FOR RESOLUTION AS OF 10 OCT 2020. PROCEDURES AND MEDICATIONS LIKELY DONE BUT WAITING FOR COMPLETE DOCUMENTATION. Was discharged on Oct 12, 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Oct 2020 14:47:15
User entered 'Went to hospital on 10/6 for an elective procedure to treat afib in heart. Ended up returning 2 days later with seeming pulmonary edema and was admitted. Covid-19 test taken and was negative. Still in Hospital but on floor not ICU. More details to come as of 10 OCT 2020. Staff found out through a scheduling call about the hospitalization on 09 OCT 2020. Found out more information on 10 Oct 2020. Waiting for resolution as of 10 Oct 2020. Procedures and medications likely done but waiting for complete documentation'	Sharon Mathys (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout flare - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:16:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:16:32
Data point term sent to Coder	System	22 Oct 2020 18:53:24
User entered 'Gout Flair'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered '10 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[None](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WHILE IN HOSPITAL FOR UNRELATED CONCERNS, HAD A GOUT FLAIRUP in the usual location of the left knee and right elbow WHICH WAS TREATED BY ANAKINRA AND PREDNISONE. FELT BETTER THE FOLLOWING DAY. WILL FOLLOW UP WITH PCP' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:54:12
User entered 'While in Hospital for unrelated concerns, had a gout flairup which was treated by anakinra and prednisone. Felt better the following day. Will follow up with PCP'	Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:32:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:52:39

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:32:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per source in association with "Multifocal Pneumonia in both lungs", the following medications were administered in the facility that have not been reported as part of "conmeds": Allopurinol (12Oct20), Diltiazem (12Oct20), Ipratropium-albuterol (08Oct20), lisinopril (12Oct20), Omeprazole (12Oct20). Please kindly review and update database. Thank you' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 21:13:34
Query 'Per source in association with "Multifocal Pneumonia in both lungs", the following medications were administered in the facility that have not been reported as part of "conmeds": Allopurinol (12Oct20), Diltiazem (12Oct20), Ipratropium-albuterol (08Oct20), lisinopril (12Oct20), Omeprazole (12Oct20). Please kindly review and update database. Thank you' answered with 'These were on file medications per the hospital records at discharge. These are unknown to the study team if the participant has been taking them. At next visit we will ask whether those have been taken in the past and which of those are still being taken.' (Site from CRA).	Sharon Mathys (b) (4)	16 Nov 2020 13:59:20
User opened query 'Per source in association with "Multifocal Pneumonia in both lungs", the following medications were administered in the facility that have not been reported as part of "conmeds": Allopurinol (12Oct20), Diltiazem (12Oct20), Ipratropium-albuterol (08Oct20), lisinopril (12Oct20), Omeprazole (12Oct20). Please kindly review and update database. Thank you' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:10:27
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:58:29

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:28:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:28:18
Data point term sent to Coder	System	14 Aug 2020 14:27:18
User entered 'Warfarin'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 14:27:17
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'Afib'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered '10'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'once daily (QD)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'Oral (ORAL)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:27:17
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:20:43
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered '11 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:20:43
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 14:27:17
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 14:27:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:43:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:43:21
Data point term sent to Coder	System	05 Oct 2020 17:42:22
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 17:41:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:30:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:30:18
Data point term sent to Coder	System	14 Aug 2020 14:29:21
User entered 'Metformin'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:38:17
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:44:08
User entered 'Type two diabetes' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:41:50
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:42:48
User entered 'HBP'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered '1000'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'once daily (QD)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'Oral (ORAL)'	Kristin Eis (b) (4)	14 Aug 2020 14:28:24
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:28:24
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:28:24
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 14:28:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:20:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:20:10
Data point term sent to Coder	System	14 Aug 2020 14:29:21
User entered 'Gabapentin'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of NEUROPOTHY) to the appropriate Medical History eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 13:08:33
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of NEUROPOTHY) to the appropriate Medical History eCRF.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:43:26
User entered 'Neuropathy'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered '300'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered 'once daily (QD)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered 'Oral (ORAL)'	Kristin Eis (b) (4)	14 Aug 2020 14:29:18
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 14:29:28
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 14:29:18
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered '1' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:29:28
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:29:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 14:29:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:29:28
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:29:18
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:29:18
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:29:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 14:29:28
User entered 'No (N)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:29:28
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:29:18
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
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)	14 Aug 2020 14:32:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:32:16
Data point term sent to Coder	System	14 Aug 2020 14:31:23
User entered 'Atorvastatin'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 14:30:23
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:09:16
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:44:28
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:44:09
User entered 'Hyperlipidemia'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered '20'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered 'once daily (QD)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered 'Oral (ORAL)'	Kristin Eis (b) (4)	14 Aug 2020 14:30:23
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:30:23
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:30:23
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:30:23
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 14:30:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:40:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:40:23
Data point term sent to Coder Coding entries removed.	System Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:39:48 22 Oct 2020 17:39:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:46:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:46:24
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6) (b) (4)	05 Oct 2020 17:45:29 05 Oct 2020 17:44:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:39:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:39:21
Data point term sent to Coder User entered 'Metoprolol'	System Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:31:24 14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 14:31:20
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered 'HYPERTENSION / Afib' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:39:39
User closed query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:10:17
Query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:44:44
User entered 'hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:44:39
User opened query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:44:35
User entered 'BP'	Kristin Eis (b) (4)	14 Aug 2020 14:31:20
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:31:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 14:31:36
User entered '25' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:31:36
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:31:20
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	14 Aug 2020 14:31:36
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	14 Aug 2020 14:31:20
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered empty; reason for change Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:31:36
User entered '25'	(b) (4)	
	Kristin Eis (b) (4)	14 Aug 2020 14:31:20
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered 'once daily (QD)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered 'Oral (ORAL)'	Kristin Eis (b) (4)	14 Aug 2020 14:31:20
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:31:20
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered '1'	Kristin Eis (b) (4)	14 Aug 2020 14:31:20
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:39:05
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	22 Oct 2020 17:39:05
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	22 Oct 2020 17:38:59
User entered '26 Sep 2017' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:38:59
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:31:20
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:00:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:00:20
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Oct 2020 17:45:29 05 Oct 2020 17:45:18
User entered 'FUROSeMIDE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:45:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:19:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:19:09
Data point term sent to Coder User entered 'FUROSAMIDE'	System Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:26 14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'chf'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered '40'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'once daily (QD)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'Oral (ORAL)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:32:23
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered '1'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:46:24
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered '26 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:46:24
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'No (N)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 14:32:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:21:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:21:17
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Oct 2020 17:46:30 05 Oct 2020 17:45:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:48:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 16:48:24
Data point term sent to Coder	System	14 Aug 2020 14:35:32
Data point term sent to Coder	System	14 Aug 2020 14:33:29
User entered 'DILTIAZAM'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 14:33:28
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User closed query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' (Site from DM). Query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:11:34
User entered 'Afib' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:45:35
User opened query 'Per DM CLR: Please note, this abbreviations for medications should not be used and full terms should be listed instead. Please review and provide full terms to reflect the underlying medical condition that this medication was used to treat/prevent. Please reconcile with the AE or Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:45:31
User entered 'bp'	Kristin Eis (b) (4) (b) (4)	24 Sep 2020 05:45:11
		14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered '240'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered 'mg (mg)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:34:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 14:34:13
User entered 'once daily (QD)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:34:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Aug 2020 14:33:28
User entered empty.	System	14 Aug 2020 14:33:28
	Kristin Eis (b) (4)	14 Aug 2020 14:33:28
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:34:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 14:34:34
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:34:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Aug 2020 14:33:28
User entered empty.	System	14 Aug 2020 14:33:28
	Kristin Eis (b) (4)	14 Aug 2020 14:33:28
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:33:28
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 14:34:34
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 14:33:28
User entered empty.	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered '1' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:34:34
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:34:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 14:34:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:34:34
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:33:28
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:33:28
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:59
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:34:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 14:34:34
User entered 'No (N)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:34:34
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 14:33:28
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:34:13
User entered empty.	System	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 14:34:13
User entered empty.	System	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 14:34:13
User entered empty.	System	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:39:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:39:22
Data point term sent to Coder	System	22 Oct 2020 17:40:49
User entered 'Metoprolol'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered 'Hypertension/Afib'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered '25'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered 'twice daily (BID)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered '26 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:56
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 17:40:11

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:44:49
Data point term sent to Coder	System	22 Oct 2020 17:42:55
User entered 'Digoxin'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered 'Atrial fibrillation'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered '125'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered 'ug (ug)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered '28 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered '12 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:49:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:49:33
Data point term sent to Coder	System	22 Oct 2020 17:48:07
User entered 'Furosemide'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered 'CHF'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered '40'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered 'twice daily (BID)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered '27 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 17:47:07

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:50:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:50:36
Data point term sent to Coder	System	22 Oct 2020 17:53:16
User entered 'Digoxin'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered 'Atrial Flutter with RVR'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered '250'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered 'ug (ug)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered 'twice daily (BID)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered '25 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered '25 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:04:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:04:27
Data point term sent to Coder	System	22 Oct 2020 18:09:50
User entered 'Vancomycin'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:13:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 18:13:48
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:13:48
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:09:50
User entered empty.	Sharon Mathys (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered 'Multifocal Pneumonia in both lungs'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered '1000'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered 'Intravenous (INTRAVENOUS)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered '08 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered '09 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: PIPERACILLIN/TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 18:29:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 18:29:09
Data point term sent to Coder	System	22 Oct 2020 18:13:57
User entered 'Piperacillin/tazobactam'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered 'Multifocal Pneumonia in both Lungs'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered '4.5g'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered 'g (g)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered 'every 8 hours'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered 'Intravenous (INTRAVENOUS)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered '8 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered '11 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:04:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:04:27
Data point term sent to Coder	System	22 Oct 2020 18:15:59
User entered 'vancomycin'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered 'Multifocal Pneumonia in both lungs'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered '1250'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered 'Intravenous (INTRAVENOUS)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered '09 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered '11 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:35
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 06:15:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 06:15:44
Data point term sent to Coder	System	22 Oct 2020 18:18:02
Data point term sent to Coder	System	22 Oct 2020 18:17:02
User entered 'Levofloxacin'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:17:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 18:17:16
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:17:16
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:17:01
User entered empty.	Sharon Mathys (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:17:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 18:17:16
User entered 'Multifocal Pneumonia in both lungs' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:17:16
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:17:01
User entered empty.	Sharon Mathys (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered '750'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered '11 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered '14 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:12
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 05:54:44
Data point term sent to Coder	System	22 Oct 2020 18:19:04
User entered 'Flagyl'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:18:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 18:18:15
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:18:15
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:18:10
User entered empty.	Sharon Mathys (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered 'Multifocal Pneumonia in both lungs'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered '500'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered 'every 8 hours'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered '11 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered '14 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 18:29:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 18:29:36
Data point term sent to Coder	System	22 Oct 2020 18:23:11
User entered 'Eliquis'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'Atrial Fibrillation'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered '5'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'every 12 hours'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered '13 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:28:47
User entered '12 Oct 2020'	Sharon Mathys (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 18:22:42

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: INTERLEUKIN INHIBITORS, PRODUCT: ANAKINRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:31:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:31:26
Data point term sent to Coder	System	22 Oct 2020 18:53:24
Data point term sent to Coder	System	22 Oct 2020 18:27:20
User entered 'anakinra'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'GOUT Flair' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 18:52:56
User entered 'Gout'	Sharon Mathys (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered '100'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered '10 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered '12 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 18:26:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:53:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:53:34
Data point term sent to Coder	System	22 Oct 2020 18:53:25
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:53:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 18:29:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 18:29:58
Data point term sent to Coder	System	22 Oct 2020 18:28:22
User entered 'Prednisone'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered 'GOUT / Gout Flair' reason for change:	Sharon Mathys (b) (4)	22 Oct 2020 18:53:08
Data Entry Error	(b) (4)	
User entered 'Gout'	Sharon Mathys (b) (4)	22 Oct 2020 18:28:17
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered '5'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered '12 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:32:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristin Eis (b) (4)	11 Sep 2020 17:01:46
User entered 'No (N)' reason for change: Data Entry Error	Kristin Eis (b) (4)	14 Aug 2020 14:24:51
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:58:39

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:32:11

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:02:24

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:32:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'cardioversion'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:02:24

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Medical History (MH)'	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:02:24

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:32:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kristin Eis (b) (4) (b) (4)	11 Sep 2020 17:02:24

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:32:11

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:10:01
User entered '06 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:01:54

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:32:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:10:01
User entered 'Elective Ablation in heart for Afib'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:01:54

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:32:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:10:01
User entered 'Medical History (MH)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:01:54

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:32:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:10:01
User entered empty.	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:01:54

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'USA-US131-2020-MRNA-1273-P301000008'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Paul'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Kilgore'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'MI'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:52:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
User entered 'US'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 14:23:46
User entered '3'	System	21 Oct 2020 16:53:55
User entered '2'	System	12 Oct 2020 15:53:02
User entered '1'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'USA-US131-2020-MRNA-1273-P301000008'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Paul'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Kilgore'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'MI'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:52:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
User entered 'US'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 14:23:46
User entered '3'	System	21 Oct 2020 16:53:55
User entered '2'	System	12 Oct 2020 15:53:02
User entered '1'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
User entered '02/Oct/2020 12:58'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:52:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'USA-US131-2020-MRNA-1273-P301000008'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Paul'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Kilgore'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'MI'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:52:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
User entered 'US'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 14:23:46
User entered '3'	System	21 Oct 2020 16:53:55
User entered '2'	System	12 Oct 2020 15:53:02
User entered '1'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '12/Oct/2020 15:53'	System	12 Oct 2020 15:53:02

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 16:53:36
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 15:53:02

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'USA-US131-2020-MRNA-1273-P301000008'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Paul'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Kilgore'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'MI'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:52:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
User entered 'US'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 14:23:46
User entered '3'	System	21 Oct 2020 16:53:55
User entered '2'	System	12 Oct 2020 15:53:02
User entered '1'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '21/Oct/2020 16:53'	System	21 Oct 2020 16:53:55

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 14:23:29
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 16:53:55

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'USA-US131-2020-MRNA-1273-P301000008'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'No (N)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Yes (Y)'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Paul'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'Kilgore'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered 'MI'	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 16:58:46
User entered (b) (6)	System	02 Oct 2020 16:58:21

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:52:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
User entered 'US'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 14:23:46
User entered '3'	System	21 Oct 2020 16:53:55
User entered '2'	System	12 Oct 2020 15:53:02
User entered '1'	System	02 Oct 2020 16:58:53

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Oct/2020 14:23'	System	23 Oct 2020 14:23:46

US3522128

Folder: SAE USA-US131-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 14:23:46