

US3522128 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:03:33

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US3522128

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 21:25:35

Generated On: 10 Jun 2021 08:03:33

Participant ID

US3522128

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

US3522128

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3522128

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
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

US3522128

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

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 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (2)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	PAST OF STROKE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)	

US3522128

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	HYPERPARATHYROIDISM
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (4)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	CHF
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (5)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	CAD
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (6)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	CKD STAGE 3
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (8)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	AFIB
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	CARDIOMYOPATHY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (10)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (11)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

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 <input checked="" type="radio"/> No <input type="radio"/>
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 (12)

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Condition	DIABETIC AUTONOMIC NEUROPATHY ASSOCIATED WITH TYPE 2 DIABETES MELLITUS- GENERALIZED PERIPHERAL PAIN AND NUMBNESS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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: Vital Signs

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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 ☒

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
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

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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		

US3522128

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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 ☒

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EAB) (1725)

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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 ☐

PRODUCTION RELEASE (v12.003

59 of 3029

EAB) (1725)

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
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)

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

TIMEPOINT

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

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

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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 ☒

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EAB) (1725)

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US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:03:33

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Yes <input type="checkbox"/>	
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: 10 Jun 2021 08:03:33

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 ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 16 Feb 2021 17:43:39

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	25 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	13:03 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 13:03
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	59 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 NOV 2020
Collection time (00:00-23:59)	13:23 (24 HR)
Collection date and time (derived)	25 NOV 2020 13:23

US3522128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:43:44

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

25 NOV 2020 13:17:47

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: 10 Jun 2021 08:03:33

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

Date and time of submission

30 NOV 2020 20:22:02

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: 10 Jun 2021 08:03:33

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

Date and time of submission

09 DEC 2020 18:06:46

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: 10 Jun 2021 08:03:33

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

Date and time of submission

16 DEC 2020 20:06:17

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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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
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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

07 JAN 2021 12:01:39

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: 10 Jun 2021 08:03:33

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

Date and time of submission

14 JAN 2021 10:04:25

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Date and time of submission

26 JAN 2021 12:03:28

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: 10 Jun 2021 08:03:33

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 FEB 2021 15:20:11
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: 10 Jun 2021 08:03:33

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

Date and time of submission

07 FEB 2021 06:01:46

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: 10 Jun 2021 08:03:33

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

Date and time of submission

17 FEB 2021 09:21:59

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: 10 Jun 2021 08:03:33

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

Date and time of submission

26 FEB 2021 02:59:19

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: 10 Jun 2021 08:03:33

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 14:35:07
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: 10 Jun 2021 08:03:33

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

Date and time of submission

07 MAR 2021 06:39:45

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

Date and time of submission

21 MAR 2021 08:08:28

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: 10 Jun 2021 08:03:33

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

Date and time of submission

30 MAR 2021 18:15:45

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: 10 Jun 2021 08:03:33

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

Date and time of submission

06 APR 2021 12:07:02

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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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: 10 Jun 2021 08:03:33

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

Date and time of submission

22 APR 2021 15:19:14

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: 10 Jun 2021 08:03:33

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

Date and time of submission

28 APR 2021 18:10:49

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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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°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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. 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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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: 10 Jun 2021 08:03:33

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°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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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°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: 10 Jun 2021 08:03:33

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

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

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: 10 Jun 2021 08:03:33

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°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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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°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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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°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: 10 Jun 2021 08:03:33

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:03:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 14:34:45

US3522128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3522128

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 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

US3522128

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 JAN 2021

Please select one status for the follow-up contact
Contact Made ☐
Contact Not Made ☒

Comments NUMBER NOT IN SERVICE

If Contact Not Made, please provide Comments

US3522128

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 FEB 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 18:56:33

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 18:56:33

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 APR 2021
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	1 APR 2021 14:20
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	133 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	26 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 18:56:32

Generated On: 10 Jun 2021 08:03:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 APR 2021

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

US3522128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 18:56:32

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 APR 2021

Collection time (00:00-23:59)

14:15 (24 HR)

Collection date and time (derived)

1 APR 2021 14:15

US3522128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 18:56:32

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 22:31:31

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 APR 2021

Please select one status for the follow-up contact Contact Made ☒ Contact Not Made ☐

Comments SEE SOURCE NOTE

If Contact Not Made, please provide Comments

US3522128

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522128

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:03:33

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3522128

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:03:33

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	3 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:03:48

Generated On: 10 Jun 2021 08:03:33

Date of updated informed consent (<i>dd MMM yyyy</i>)	3 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	5 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 FEB 2021
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 12:14
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	95 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)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 FEB 2021
Time of assessment (00:00-23:59)	13:17 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 13:17
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 FEB 2021

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

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 FEB 2021

What was the treatment time? (00:00-23:59) 12:47 (24 HR)

Treatment Date and Time (derived) 3 FEB 2021 12:47

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 FEB 2021
Collection time (00:00-23:59)	12:40 (24 HR)
Collection date and time (derived)	3 FEB 2021 12:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 FEB 2021
Collection time (00:00 - 23:59)	12:35
Collection Date and Time (derived)	3 FEB 2021 12:35

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:33:49

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

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

US3522128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3522128

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:33:48

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 15:33:49

Generated On: 10 Jun 2021 08:03:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 09:36
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 15:33:49

Generated On: 10 Jun 2021 08:03:33

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 10:10
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3522128

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:33:48

Generated On: 10 Jun 2021 08:03:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 MAR 2021

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

US3522128

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 15:33:48

Generated On: 10 Jun 2021 08:03:33

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 MAR 2021

What was the treatment time? (00:00-23:59) 09:40 (24 HR)

Treatment Date and Time (derived) 3 MAR 2021 09:40

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:33:48

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 15:16:29

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 MAR 2021

Please select one status for the follow-up contact Contact Made ☒
Contact Not Made ☐

Comments PT STATES HE FELT FATIGUED
UNTIL THE NEXT DAY WHEN
HE WOKE UP. RESOLVED
AROUND 6-8 HOURS AFTER ON
04 MAR 2021 ACCORDING TO
PT. DENIES ANY OTHER ISSUES
AT THIS TIME. CONTINUED IN
SOURCE

If Contact Not Made, please provide Comments

US3522128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 15:16:29

Generated On: 10 Jun 2021 08:03:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522128

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 18:56:32

Generated On: 10 Jun 2021 08:03:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 18:56:32

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 APR 2021
Time of assessment (<i>00:00-23:59</i>)	14:20 (24 HR)
Vital Signs Date and Time (derived)	1 APR 2021 14:20
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	133 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	26 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522128

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 18:56:32

Generated On: 10 Jun 2021 08:03:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 APR 2021

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

US3522128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 18:56:32

Generated On: 10 Jun 2021 08:03:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	1 APR 2021
Collection time (<i>00:00-23:59</i>)	14:15 (24 HR)
Collection date and time (derived)	1 APR 2021 14:15

US3522128

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 21:25:35

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

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EAB) (1725)

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US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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: 10 Jun 2021 08:03:33

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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: 10 Jun 2021 08:03:33

AEID	USA-US131-2020-MRNA-1273-P30 1000008
Adverse event	ATRIAL FLUTTER WITH RAPID VENTRICULAR RESPONSE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

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. WAS TESTED ON 25SEP2020 IN HOSPITAL FOR SARS-COV-2 BY PCR AND TESTED NEGATIVE.	
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: 10 Jun 2021 08:03:33

AEID	USA-US131-2020-MRNA-1273-P30 1000008
Adverse event	MULTIFOCAL PNEUMONIA IN BOTH LUNGS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	8 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

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):
PT 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

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

THE ED. THERE WERE NO
APPARENT SIGNS OF
CONGESTIVE HEART FAILURE.
HIS BNP WAS 541. 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: 10 Jun 2021 08:03:33

AEID

Adverse event

GOUT FLAIR (LEFT KNEE AND
RIGHT ELBOW)

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

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Folder: Adverse Events

Form: Adverse Events (7)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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

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Folder: Adverse Events

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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)	

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Folder: Adverse Events

Form: Adverse Events (8)

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AEID	USA-US131-2021-MRNA-1273-P30 1000015
Adverse event	RECURRENT PAROXYSMAL ATRIAL FIBRILLATION STATUS POST MULTIPLE FAILED ABLATIONS AND MEDICAL/DIRECT CARDIOVERSIONS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	1 APR 2021
Hospital Discharge Date (dd MMM yyyy)	04 APR 2021
Admitted to ICU?	

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Folder: Adverse Events

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	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
	Unknown <input type="radio"/>
<hr/>	
Number of Days in ICU	
<hr/>	
Persistent or significant disability or incapacity	False
<hr/>	
Congenital anomaly or birth defect	False
<hr/>	
Other medically important event	True
<hr/>	
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
<hr/>	
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
<hr/>	
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
<hr/>	
Other action taken (check all that apply)	
<hr/>	
None	True
<hr/>	
Concomitant Medication	False
<hr/>	
Concomitant Procedure	False
<hr/>	
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input checked="" type="radio"/>
<hr/>	
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
<hr/>	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (8)

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WHEN ASKED ABOUT MED HX
AND CURRENT HEALTH
STATUS PT REPORTED "I FELT
MYSELF GO BACK INTO A-FIB
ABOUT A WEEK AGO", HE IS
NOTICEABLY SHORTNESS OF
BREATH WITH ACTIVITY, AND
REPORTS BEING SLIGHTLY
LIGHTHEADED WHEN HE
CHANGES FROM SITTING TO
STANDING TOO QUICKLY. HE
HAD ALREADY CONTACTED
HIS CARDIOLOGIST AND HAS
APPOINTMENT SET UP FOR 4/7.
HOWEVER, UPON ASSESSING
VITALS IT WAS FOUND THAT
HIS HR WAS FLUCTUATING
BETWEEN 121-135. APPLE
WATCH
ELECTROCARDIOGRAM
FEATURE CONFIRMED MY
FINDINGS WITH NOTICEABLE
IRREGULARITIES. PT WAS
ADVISED TO CALL
CARDIOLOGIST BEFORE
LEAVING CLINIC. DR. KILGORE,
STUDY PHYSICIAN, WAS ALSO
NOTIFIED AND INTERVIEWED
PT. AFTER SPEAKING WITH
CARDIOLOGY PA AND (b) (6)
(b) (6) IT WAS DETERMINED
THAT PT SHOULD GO TO
NORTHVILLE URGENT CARE
FOR AN
ELECTROCARDIOGRAM,
ORDERED BY (b) (6)
OFFICE. I SUGGESTED MAYBE

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Folder: Adverse Events

Form: Adverse Events (8)

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ER WOULD BE BETTER OPTION
DUE TO SYMPTOMS AND RATE
AS URGENT CARE WOULD
MORE THAN LIKELY
TRANSFER TO ER. PATIENT
(b) (6) AND WILL
HAVE WIFE DRIVE HIM TO
EITHER URGENT CARE OR ER.
PATIENT AOX4 AND REPORTS
BEING CAPABLE OF GETTING
HIMSELF TO ER VIA PRIVATE
AUTO. PT HAS HISTORY OF
MULTIPLE ABLATIONS AND
CARDIOVERTS. EDUCATION
PROVIDED, PT AWARE THAT
HE SHOULD BE MONITORING
RATE AS WELL AS RHYTHM
AND TO REPORT SYMPTOMS IN
THEIR ENTIRETY TO
CARDIOLOGIST. SPOKE WITH
PATIENT 4/2 AND HE REPORTS
THAT HE DID GO TO ER, EKG
SHOWED AFIB RVR, THEY
ADMITTED HIM FOR
CARDIOLOGY CONSULT,
POSSIBLE ABLATION, WILL
UPDATE WHEN POSSIBLE.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 21:25:35

Generated On: 10 Jun 2021 08:03:33

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)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 22:31:30

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 22:31:30

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 22:31:30

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 22:31:30

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 22:31:30

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2017
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 22:31:30

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

Name of Medication	DILTIAZAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	AFIB
Dose per administration	240
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 22:31:30

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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

EVERY 8 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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

EVERY 8 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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

EVERY 12 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

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 ☐

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EAB) (1725)

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication A-FIB

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

Name of Medication DILTIAZEM

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 180

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

ONCE AT NIGHT

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 400

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 200

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

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 ☐

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EAB) (1725)

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

Name of Medication POTAASSIUM CHLORIDE
(K-TAB)

Prophylaxis Yes ☐
No ☒

Indication CHRONIC SYSTOLIC HEART
FAILURE

Dose per administration 20

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MEQ

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 14 Apr 2021 22:31:30

Generated On: 10 Jun 2021 08:03:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 21:25:35

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 AUG 2020	CARDIOVERSION	Medical History	
12 OCT 2020	ELECTIVE ABLATION IN HEART FOR AFIB	Medical History	
08 OCT 2020	XRAY CHEST PORTABLE 1 VIEW	Adverse Event	
08 OCT 2020	ELECTROPHYSIOLOGY STUDY	Adverse Event	
08 OCT 2020	EMERGENCY DEPARTMENT ULTRASOUND CARDIAC	Adverse Event	
08 OCT 2020	CT CHEST	Adverse Event	
12 OCT 2020	EKG 12 LEAD	Adverse Event	
09 OCT 2020	HEATED HIGH FLOW NASAL CANNULA	Adverse Event	
09 OCT 2020	BLOOD CULTURE	Adverse Event	
09 OCT 2020	SPUTUM CULTURE	Adverse Event	
8 OCT 2020	PROTIME WITH INR (BLOOD DRAW)	Adverse Event	
8 OCT 2020	CARDIAC PROFILE (BLOOD DRAW)	Adverse Event	

US3522128

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10

US3522128

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

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
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)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
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)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
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)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
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

US3522128

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

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
Date of submission (Pre-filled from custom function)	30/NOV/2020 13:35
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 (6)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
Date of submission (Pre-filled from custom function)	11/DEC/2020 08:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522128

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

Form: Safety Report Form (7)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
Date of submission (Pre-filled from custom function)	15/DEC/2020 13:07
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 (8)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
Date of submission (Pre-filled from custom function)	21/DEC/2020 13:33
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 (9)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
Date of submission (Pre-filled from custom function)	19/JAN/2021 18:28
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 (10)

Data signed: (b) (4) 21 Feb 2021 21:25:36

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	10
Date of submission (Pre-filled from custom function)	04/FEB/2021 10:20
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-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 14 Apr 2021 22:31:31

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Apr 2021 22:31:31

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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/APR/2021 14:54
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-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 14 Apr 2021 22:31:31

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	05/APR/2021 11:20
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-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 14 Apr 2021 22:31:31

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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/APR/2021 10:38
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-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 14 Apr 2021 22:31:31

Generated On: 10 Jun 2021 08:03:33

SAEID	USA-US131-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	13/APR/2021 10:33
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: 10 Jun 2021 08:03:33

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'US3522128'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 13:44:16

US3522128

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:46:35

US3522128

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:44:17

US3522128

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Clinic (Clinic)'	Kristin Eis (b) (4)	14 Aug 2020 13:46:35

US3522128

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered 'SCRN'	System	14 Aug 2020 13:46:35

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 13:44:18

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '70'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered 'YEARS'	System	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered '70'	System	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Male (M)'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:03:33

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:47:06

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '14 Aug 2020'	Kristin Eis (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered 'Aug 2020'	System	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered '2020'	System	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Amendment 1 (1)'	Kristin Eis (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:47:21

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:44:17

US3522128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:03:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered 'I'	System	14 Aug 2020 13:47:27

US3522128

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:47:27

US3522128

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:03:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:54:15

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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) (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, HLG: 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 diabetes'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 13:54:29

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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)	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)	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)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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) (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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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)	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:10:27

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User coded data point as SOC: Endocrine disorders, HLTG: Parathyroid gland disorders, HLT: Hyperparathyroid disorders, PT: Hyperparathyroidism, LLT: Hyperparathyroidism - 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 'HYPERPARATHYROIDISM'	Kristin Eis (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:10:59

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User coded data point as SOC: Cardiac disorders, HLGHT: 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

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:11:20

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 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 'CAD'	Kristin Eis (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:11:41

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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)	
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).	(b) (4), (b) (6)	09 Sep 2020 15:10:34
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).	mayur ramesh (b) (4)	08 Sep 2020 12:43:25
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.	(b) (4), (b) (6)	04 Sep 2020 15:23:33
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	(b) (4)	
User entered 'CKD stage 3'	System	14 Aug 2020 14:12:41
	Kristin Eis (b) (4)	14 Aug 2020 14:12:07
	(b) (4)	

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:12:07

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User coded data point as SOC: Vascular disorders, HLT: 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

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:12:36

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:13:00

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	14 Aug 2020 14:13:38

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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).	(b) (4) 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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	05 Oct 2020 17:46:11

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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)	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)	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)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	22 Oct 2020 18:24:16

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User coded data point as SOC: Nervous system disorders, HLGT: Neuromuscular disorders, HLT: Autonomic nervous system disorders, PT: Diabetic autonomic neuropathy, LLT: Diabetic peripheral autonomic neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 10:29:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 10:29:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:03:48
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 06:38:02
Data point term sent to Coder	System	16 Mar 2021 18:03:07
User entered 'DIABETIC AUTONOMIC NEUROPATHY ASSOCIATED WITH TYPE 2 DIABETES MELLITUS- generalized PERIPHERAL PAIN AND NUMBNESS' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 18:02:57
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	16 Mar 2021 18:02:49
' answered with 'updated' (Site from DM).		
User entered 'DIABETIC AUTONOMIC NEUROPATHY ASSOCIATED WITH TYPE 2 DIABETES MELLITUS- peripheral pain and numbness' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 18:02:43
Data point term sent to Coder	System	16 Mar 2021 17:59:48
Coding entries removed.	(b) (4), (b) (6)	16 Mar 2021 17:59:23
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 17:59:23

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

Condition

Audit	User	Time (GMT)
User entered 'Diabetic autonomic neuropathy associated with type 2 diabetes mellitus' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 17:59:23
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	10 Mar 2021 03:08:09
' (Site from DM).		
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Feb 2021 15:07:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:07:00
Data point term sent to Coder	System	23 Feb 2021 15:06:11
User entered 'Neuropathy'	(b) (4), (b) (6)	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered empty.	System	23 Feb 2021 15:05:15

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '14 Aug 2020'	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '9:50'	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered '14 Aug 2020 9:50'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '70' in	Kristin Eis (b) (4)	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: 10 Jun 2021 08:03:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '240' lb	Kristin Eis (b) (4)	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: 10 Jun 2021 08:03:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
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: 10 Jun 2021 08:03:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
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: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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) (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) (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) (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered 'bpm'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered 'breaths/min'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered 'mmHg'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	Kristin Eis (b) (4)	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User entered 'mmHg'	System	14 Aug 2020 13:49:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14

US3522128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14

US3522128

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:47:39

US3522128

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (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).	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

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)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'I'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:03:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:53:43

US3522128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:49:33

US3522128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '14 Aug 2020'	Kristin Eis (b) (4)	14 Aug 2020 13:49:33

US3522128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Clinic (Clinic)'	Kristin Eis (b) (4)	14 Aug 2020 13:49:33

US3522128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'VISIT1'	System	14 Aug 2020 13:49:33

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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: 10 Jun 2021 08:03:33

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) 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) (b) (4)	14 Aug 2020 13:44:24

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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)	14 Aug 2020 13:52:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Aug 2020 13:51:19
User entered empty.	System	14 Aug 2020 13:51:19
	Kristin Eis (b) (4)	14 Aug 2020 13:51:19
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
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)	14 Aug 2020 13:52:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 13:51:19
	Kristin Eis (b) (4)	14 Aug 2020 13:51:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:51:19

US3522128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:51:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:03:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 13:51:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '68' in	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Aug 2020 14:19:19
User entered '240' lb reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '140' lb	(b) (4)	17 Aug 2020 14:19:19
	Kristin Eis (b) (4)	14 Aug 2020 13:51:39
	(b) (4)	14 Aug 2020 13:51:39
	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	14 Aug 2020 13:49:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Aug 2020 14:19:19
User entered '68' in	Sharon Mathys (b) (4)	14 Aug 2020 13:49:55
	Kristin Eis (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Aug 2020 14:19:19
User entered '240' lb reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:19
User entered '140' lb	(b) (4)	17 Aug 2020 14:19:19
	Kristin Eis (b) (4)	14 Aug 2020 13:51:39
	(b) (4)	14 Aug 2020 13:51:39
	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	14 Aug 2020 13:49:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User accepted default value 'Pre-Dose (PREDOSE)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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)	14 Aug 2020 13:51:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	14 Aug 2020 13:49:55
User entered empty.	System	14 Aug 2020 13:49:55
	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Kristin Eis (b) (4)	14 Aug 2020 13:51:01
User entered empty.	(b) (4)	
	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered '14 Aug 2020 9:50'	System	14 Aug 2020 13:51:01
User entered empty.	System	14 Aug 2020 13:49:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '18' reason for change: Data Entry Error	(b) (4)	14 Aug 2020 13:51:01
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:49:55
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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) (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) (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) (b) (4)	14 Aug 2020 13:51:01
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: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Aug 2020 14:19:19
User entered '68' in	Sharon Mathys (b) (4)	14 Aug 2020 13:49:55
	Kristin Eis (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Aug 2020 14:19:19
User entered '240' lb reason for change: Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 13:51:39
User entered '140' lb	Kristin Eis (b) (4)	14 Aug 2020 13:49:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User accepted default value 'Post-Dose (POSTDOSE)'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 13:49:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '14 Aug 2020' reason for change: Data Entry Error	(b) (4)	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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) (4), (b) (6)	17 Aug 2020 15:59:21
User opened query 'Post-dose vital signs time is prior System 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) (b) (4)	14 Aug 2020 13:49:55

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	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: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	17 Sep 2020 13:30:30
	(b) (4)	
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
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '58' reason for change: Data Entry Error	(b) (4) (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: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '16' reason for change: Data Entry Error	(b) (4) (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: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '113' reason for change: Data Entry Error	(b) (4) (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: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '70' reason for change: Data Entry Error	(b) (4)	
	(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: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	17 Aug 2020 14:19:49
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:53:04
	(b) (4)	

US3522128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 14:19:49
User entered '14 Aug 2020'	Kristin Eis (b) (4)	14 Aug 2020 13:53:04

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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).	(b) (4)	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)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '14 Aug 2020'	Kristin Eis (b) (4)	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '10:26' reason for change: Data Entry Error	(b) (4) (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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'ONCE'	System	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 13:53:57

US3522128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:35:11

US3522128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '14 Aug 2020'	Kristin Eis (b) (4)	14 Aug 2020 14:35:11

US3522128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '10:15'	Kristin Eis (b) (4)	14 Aug 2020 14:35:11

US3522128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '14 Aug 2020'	Kristin Eis (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '10:17'	Kristin Eis (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'No (N)'	Kristin Eis (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered empty.	Kristin Eis (b) (4)	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered empty.	System	14 Aug 2020 14:35:28

US3522128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	14 Aug 2020 13:49:19

US3522128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered '1'	System	14 Aug 2020 13:49:19

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	14 Aug 2020 14:56:27
	System	14 Aug 2020 14:56:27

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '97.3'	System	14 Aug 2020 14:56:27
	System	14 Aug 2020 14:56:27

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	15 Aug 2020 00:47:20
	System	15 Aug 2020 00:47:20

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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
	System	15 Aug 2020 00:47:20

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '14 Aug 2020 20:47'	System	15 Aug 2020 00:47:20
	System	15 Aug 2020 00:47:20

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	16 Aug 2020 02:37:32
	System	16 Aug 2020 02:37:32

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '99.6'	System	16 Aug 2020 02:37:32
	System	16 Aug 2020 02:37:32

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '15 Aug 2020 22:37'	System	16 Aug 2020 02:37:32
	System	16 Aug 2020 02:37:32

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	17 Aug 2020 00:40:08
	System	17 Aug 2020 00:40:08

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '99.9'	System	17 Aug 2020 00:40:08
	System	17 Aug 2020 00:40:08

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	17 Aug 2020 00:40:08
	System	17 Aug 2020 00:40:08

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '16 Aug 2020 20:40'	System	17 Aug 2020 00:40:08
	System	17 Aug 2020 00:40:08

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	20 Aug 2020 03:54:42
	System	20 Aug 2020 03:54:42

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '97.9'	System	20 Aug 2020 03:54:42
	System	20 Aug 2020 03:54:42

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	20 Aug 2020 03:54:42
	System	20 Aug 2020 03:54:42

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '19 Aug 2020 23:54'	System	20 Aug 2020 03:54:42
	System	20 Aug 2020 03:54:42

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	21 Aug 2020 01:51:11
	System	21 Aug 2020 01:51:11

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '98.1'	System	21 Aug 2020 01:51:11
	System	21 Aug 2020 01:51:11

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	21 Aug 2020 01:51:11
	System	21 Aug 2020 01:51:11

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '20 Aug 2020 21:51'	System	21 Aug 2020 01:51:11
	System	21 Aug 2020 01:51:11

US3522128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	14 Aug 2020 14:59:27
	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	14 Aug 2020 14:59:27
	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (1)'	System	14 Aug 2020 14:59:27
	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '14 Aug 2020 10:59'	System	14 Aug 2020 14:59:27
	System	14 Aug 2020 14:59:27

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (1)'	System	15 Aug 2020 00:49:18
	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	15 Aug 2020 00:49:18
	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	15 Aug 2020 00:49:18
	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (1)'	System	15 Aug 2020 00:49:18
	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '14 Aug 2020 20:49'	System	15 Aug 2020 00:49:18
	System	15 Aug 2020 00:49:18

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (1)'	System	17 Aug 2020 00:41:37
	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	17 Aug 2020 00:41:37
	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	17 Aug 2020 00:41:37
	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (1)'	System	17 Aug 2020 00:41:37
	System	17 Aug 2020 00:41:37

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (1)'	System	21 Aug 2020 01:51:34
	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	21 Aug 2020 01:51:34
	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	21 Aug 2020 01:51:34
	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (1)'	System	21 Aug 2020 01:51:34
	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '20 Aug 2020 21:51'	System	21 Aug 2020 01:51:34
	System	21 Aug 2020 01:51:34

US3522128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	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: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '14 Aug 2020 11:00'	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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	15 Aug 2020 00:51:00
	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	15 Aug 2020 00:51:00
	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	15 Aug 2020 00:51:00
	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	15 Aug 2020 00:51:00
	System	15 Aug 2020 00:51:00

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	16 Aug 2020 02:40:44
	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	16 Aug 2020 02:40:44
	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	16 Aug 2020 02:40:44
	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	16 Aug 2020 02:40:44
	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	16 Aug 2020 02:40:44
	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '15 Aug 2020 22:40'	System	16 Aug 2020 02:40:44
	System	16 Aug 2020 02:40:44

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	17 Aug 2020 00:42:39
	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	17 Aug 2020 00:42:39
	System	17 Aug 2020 00:42:39

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	20 Aug 2020 03:56:40
	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No interference with activity (1)'	System	20 Aug 2020 03:56:40
	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	20 Aug 2020 03:56:40
	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	20 Aug 2020 03:56:40
	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	20 Aug 2020 03:56:40
	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	20 Aug 2020 03:56:40
	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	20 Aug 2020 03:56:40
	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '19 Aug 2020 23:56'	System	20 Aug 2020 03:56:40
	System	20 Aug 2020 03:56:40

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	21 Aug 2020 01:52:04
	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	21 Aug 2020 01:52:04
	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	21 Aug 2020 01:52:04
	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	21 Aug 2020 01:52:04
	System	21 Aug 2020 01:52:04

US3522128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	22 Aug 2020 13:52:26
	System	22 Aug 2020 13:52:26

US3522128

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '22 Aug 2020 09:52'	System	22 Aug 2020 13:52:26
	System	22 Aug 2020 13:52:26

US3522128

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4)	21 Aug 2020 19:35:47

US3522128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '21 Aug 2020'	Jo-Ann Rammal (b) (4)	21 Aug 2020 19:35:47

US3522128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Contact Made (CONTACT MADE)'	Jo-Ann Rammal (b) (4)	21 Aug 2020 19:35:47

US3522128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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) (4), (b) (6)	04 Sep 2020 19:46:00
User entered 'Pt is doing good, no adverse events'	Jo-Ann Rammal (b) (4) (b) (4)	21 Aug 2020 19:35:47

US3522128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4)	21 Aug 2020 19:35:53

US3522128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'I'	System	21 Aug 2020 19:35:53

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:41:05

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:41:05

US3522128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'not done'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:41:05

US3522128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:41:19

US3522128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'I'	System	04 Sep 2020 19:41:19

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:41:52

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:41:52

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:41:52

US3522128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
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) (4), (b) (6)	04 Sep 2020 19:41:52

US3522128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:41:56

US3522128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'I'	System	04 Sep 2020 19:41:56

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	11 Sep 2020 16:58:39

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '11 Sep 2020'	Kristin Eis (b) (4)	11 Sep 2020 16:58:39

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Clinic (Clinic)'	Kristin Eis (b) (4)	11 Sep 2020 16:58:39

US3522128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'VISIT2'	System	11 Sep 2020 16:58:39

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '11 Sep 2020'	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '12:59'	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '98.1' F	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Other (Other)'	(b) (4) Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'temporal'	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '58'	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'bpm'	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '14'	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '100'	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'mmHg'	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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) (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: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'mmHg'	System	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '14:04' reason for change: Data Entry Error	(b) (4)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '97.6' F reason for change: Data Entry Error	(b) (4)	11 Sep 2020 18:08:42
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:00:31

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	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: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4)	
	(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: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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

US3522128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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) (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: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	11 Sep 2020 17:00:36

US3522128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	
User entered '11 Sep 2020' reason for change: Data Entry Error	System	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).	Kristin Eis (b) (4)	11 Sep 2020 17:00:45
User entered empty.	(b) (4)	
	System	11 Sep 2020 17:00:36
	Kristin Eis (b) (4)	11 Sep 2020 17:00:36
	(b) (4)	

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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).	(b) (4)	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)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '11 Sep 2020'	Kristin Eis (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '13:34' reason for change: Data Entry Error	(b) (4)	11 Sep 2020 17:39:40
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Left Arm (LEFT ARM)'	Kristin Eis (b) (4)	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'ONCE'	System	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 17:01:20

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:39:06

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:39:06

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '13:20'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:39:06

US3522128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '11 Sep 2020'	(b) (4) (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: 10 Jun 2021 08:03:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	(b) (4) (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: 10 Jun 2021 08:03:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '13:25'	(b) (4) (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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
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: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'No (N)'	(b) (4) (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: 10 Jun 2021 08:03:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered empty.	(b) (4) (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: 10 Jun 2021 08:03:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered empty.	System	11 Sep 2020 17:39:21

US3522128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	Kristin Eis (b) (4)	11 Sep 2020 17:01:25

US3522128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered '1'	System	11 Sep 2020 17:01:25

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	12 Sep 2020 01:34:40
	System	12 Sep 2020 01:34:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '97.2'	System	12 Sep 2020 01:34:40
	System	12 Sep 2020 01:34:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '11 Sep 2020 21:34'	System	12 Sep 2020 01:34:40
	System	12 Sep 2020 01:34:40

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	13 Sep 2020 01:52:17
	System	13 Sep 2020 01:52:17

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '97.6'	System	13 Sep 2020 01:52:17
	System	13 Sep 2020 01:52:17

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '12 Sep 2020 21:52'	System	13 Sep 2020 01:52:17
	System	13 Sep 2020 01:52:17

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	System	15 Sep 2020 12:19:56
	System	15 Sep 2020 12:19:56

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '95.3'	System	15 Sep 2020 12:19:56
	System	15 Sep 2020 12:19:56

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	15 Sep 2020 12:19:56
	System	15 Sep 2020 12:19:56

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'Yes (Y)'	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: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '97.5'	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '11 Sep 2020 14:04'	System	11 Sep 2020 18:04:48
	System	11 Sep 2020 18:04:48

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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'	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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
	System	13 Sep 2020 01:54:01

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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
	System	13 Sep 2020 01:54:01

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (1)'	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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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'	System	15 Sep 2020 12:20:17
User entered '15 Sep 2020 08:20'	System	15 Sep 2020 12:20:17

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	12 Sep 2020 01:36:43
	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	12 Sep 2020 01:36:43
	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	12 Sep 2020 01:36:43
	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	12 Sep 2020 01:36:43
	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	12 Sep 2020 01:36:43
	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	System	12 Sep 2020 01:36:43
	System	12 Sep 2020 01:36:43

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered '12 Sep 2020 21:53'	System	13 Sep 2020 01:53:36
	System	13 Sep 2020 01:53:36

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	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: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' 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: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'No (N)'	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: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	16 Sep 2020 14:57:30
	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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' User entered 'None (0)'	System	16 Sep 2020 14:57:30
	System	16 Sep 2020 14:57:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30

US3522128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:03:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:30
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: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4)	18 Sep 2020 15:09:47

US3522128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered '18 Sep 2020'	Jo-Ann Rammal (b) (4)	18 Sep 2020 15:09:47

US3522128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Contact Made (CONTACT MADE)'	Jo-Ann Rammal (b) (4)	18 Sep 2020 15:09:47

US3522128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
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)	18 Sep 2020 15:09:47

US3522128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4)	18 Sep 2020 15:09:56

US3522128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'I'	System	18 Sep 2020 15:09:56

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:19:37

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:19:37

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:19:37

US3522128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
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) (4), (b) (6)	25 Sep 2020 17:19:37

US3522128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:19:45

US3522128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'I'	System	25 Sep 2020 17:19:45

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:26:08

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:26:08

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:26:08

US3522128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:37:27

US3522128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'I'	System	02 Oct 2020 15:37:27

US3522128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:53

US3522128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 06:00:53
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Participant was hospitalized ' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 18:24:13
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	25 Nov 2020 18:23:53
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 18:23:53

US3522128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:23:53

US3522128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'VISIT3'	System	25 Nov 2020 18:23:53

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '13:03'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered '25 Nov 2020 13:03'	System	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '59'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'bpm'	System	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '18'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'breaths/min'	System	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '125'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'mmHg'	System	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '67'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'mmHg'	System	25 Nov 2020 18:24:56

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24

US3522128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24

US3522128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:25:01

US3522128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:25:01

US3522128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:25:09

US3522128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:25:09

US3522128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	25 Nov 2020 18:25:14
User entered '13:23' reason for change: Data Entry Error	System	25 Nov 2020 18:25:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 18:25:09
User entered '13:' (non-conformant).	System	25 Nov 2020 18:25:09

US3522128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered '25 Nov 2020 13:23'	System	25 Nov 2020 18:25:14
User entered '25 Nov 2020 13:' (non-conformant).	System	25 Nov 2020 18:25:09

US3522128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:43:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:25:18

US3522128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'I'	System	25 Nov 2020 18:25:18

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 64'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 71'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 78'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

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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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3522128

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 92'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered 'Day 99'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 14:29:19

US3522128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:08:47
Data entry locked.	System	14 Aug 2020 14:29:19
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 14:29:19

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-11-25T13:17:30', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b0dfad58-1f8d-45fe-88c7-effce20281ba' User entered 'No (N)'	System	25 Nov 2020 18:17:50

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-11-25T13:17:36', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b0dfad58-1f8d-45fe-88c7-effce20281ba' User entered 'No (N)'	System	25 Nov 2020 18:17:50

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-11-25T13:17:47', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b0dfad58-1f8d-45fe-88c7-effce20281ba' User entered '25 Nov 2020 13:17:47'	System	25 Nov 2020 18:17:50
	System	25 Nov 2020 18:17:50

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-11-30T20:21:45', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'edb07453-c8ec-4694-9884-549c6584fba4' User entered 'No (N)'	System	01 Dec 2020 01:22:06
	System	01 Dec 2020 01:22:06

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-11-30T20:21:51', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'edb07453-c8ec-4694-9884-549c6584fba4' User entered 'No (N)'	System	01 Dec 2020 01:22:06
	System	01 Dec 2020 01:22:06

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-11-30T20:22:02', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'edb07453-c8ec-4694-9884-549c6584fba4' User entered '30 Nov 2020 20:22:02'	System	01 Dec 2020 01:22:06
	System	01 Dec 2020 01:22:06

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-12-09T18:06:31', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0f21a90f-5339-4ed4-b7c6-d5cf30e38b25'	System	09 Dec 2020 23:06:51
User entered 'No (N)'	System	09 Dec 2020 23:06:51

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-12-09T18:06:37', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0f21a90f-5339-4ed4-b7c6-d5cf30e38b25'	System	09 Dec 2020 23:06:51
User entered 'No (N)'	System	09 Dec 2020 23:06:51

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-12-09T18:06:46', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '0f21a90f-5339-4ed4-b7c6-d5cf30e38b25' User entered '09 Dec 2020 18:06:46'	System	09 Dec 2020 23:06:51
	System	09 Dec 2020 23:06:51

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-12-16T20:06:06', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '1f291f2e-d51e-4289-bd92-c61a21eb2066'	System	17 Dec 2020 01:06:20
User entered 'No (N)'	System	17 Dec 2020 01:06:20

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-12-16T20:06:11', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '1f291f2e-d51e-4289-bd92-c61a21eb2066'	System	17 Dec 2020 01:06:20
User entered 'No (N)'	System	17 Dec 2020 01:06:20

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2020-12-16T20:06:17', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '1f291f2e-d51e-4289-bd92-c61a21eb2066'	System	17 Dec 2020 01:06:20
User entered '16 Dec 2020 20:06:17'	System	17 Dec 2020 01:06:20

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-07T12:01:30', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e476fafa-6d99-450b-8d37-bded6f3760bd' User entered 'No (N)'	System	07 Jan 2021 17:01:45
	System	07 Jan 2021 17:01:45

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-07T12:01:34', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e476fafa-6d99-450b-8d37-bded6f3760bd' User entered 'No (N)'	System	07 Jan 2021 17:01:45

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-07T12:01:39', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e476fafa-6d99-450b-8d37-bded6f3760bd' User entered '07 Jan 2021 12:01:39'	System	07 Jan 2021 17:01:45
	System	07 Jan 2021 17:01:45

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-14T10:04:10', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '66035156-2a33-4ea8-8e51-a50bd69956ae' User entered 'No (N)'	System	14 Jan 2021 15:04:28
	System	14 Jan 2021 15:04:28

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-14T10:04:16', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '66035156-2a33-4ea8-8e51-a50bd69956ae' User entered 'No (N)'	System	14 Jan 2021 15:04:28

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-14T10:04:25', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '66035156-2a33-4ea8-8e51-a50bd69956ae' User entered '14 Jan 2021 10:04:25'	System	14 Jan 2021 15:04:28
	System	14 Jan 2021 15:04:28

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-26T12:03:10', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '065eff5e-7882-4dbf-bb12-778cac342969' User entered 'No (N)'	System	26 Jan 2021 17:43:12

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-26T12:03:21', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '065eff5e-7882-4dbf-bb12-778cac342969'	System	26 Jan 2021 17:43:12
User entered 'No (N)'	System	26 Jan 2021 17:43:12

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-01-26T12:03:28', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '065eff5e-7882-4dbf-bb12-778cac342969' User entered '26 Jan 2021 12:03:28'	System	26 Jan 2021 17:43:12

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-02T15:19:44', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'efc125d0-cc14-4a9b-91a9-736cb59207b6' User entered 'Yes (Y)'	System	07 Feb 2021 13:01:22
	System	07 Feb 2021 13:01:22

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-02T15:19:49', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'efc125d0-cc14-4a9b-91a9-736cb59207b6' User entered 'No (N)'	System	07 Feb 2021 13:01:22
	System	07 Feb 2021 13:01:22

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-02T15:19:53', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'efc125d0-cc14-4a9b-91a9-736cb59207b6' User entered 'No (N)'	System	07 Feb 2021 13:01:22
	System	07 Feb 2021 13:01:22

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-02T15:20:03', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'efc125d0-cc14-4a9b-91a9-736cb59207b6' User entered 'No (N)'	System	07 Feb 2021 13:01:22
	System	07 Feb 2021 13:01:22

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-02T15:20:11', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'efc125d0-cc14-4a9b-91a9-736cb59207b6' User entered '02 Feb 2021 15:20:11'	System	07 Feb 2021 13:01:22
	System	07 Feb 2021 13:01:22

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-07T06:01:31', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b6c62c3a-a27d-4ce0-b3c9-a04a1286fbf5'	System	07 Feb 2021 13:01:49
User entered 'No (N)'	System	07 Feb 2021 13:01:49

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-07T06:01:39', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b6c62c3a-a27d-4ce0-b3c9-a04a1286fbf5'	System	07 Feb 2021 13:01:49
User entered 'No (N)'	System	07 Feb 2021 13:01:49

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-07T06:01:46', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b6c62c3a-a27d-4ce0-b3c9-a04a1286fbf5' User entered '07 Feb 2021 06:01:46'	System	07 Feb 2021 13:01:49
	System	07 Feb 2021 13:01:49

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-17T09:21:51', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e6eac3c7-9af4-4560-b5b1-07459fd395b4' User entered 'No (N)'	System	17 Feb 2021 14:22:02
	System	17 Feb 2021 14:22:02

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-17T09:21:55', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e6eac3c7-9af4-4560-b5b1-07459fd395b4' User entered 'No (N)'	System	17 Feb 2021 14:22:02

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-17T09:21:59', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'e6eac3c7-9af4-4560-b5b1-07459fd395b4' User entered '17 Feb 2021 09:21:59'	System	17 Feb 2021 14:22:02
	System	17 Feb 2021 14:22:02

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-25T21:59:08-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '8e912434-40bd-4373-868b-c164c358d21c' User entered 'No (N)'	System	26 Feb 2021 03:03:00
	System	26 Feb 2021 03:03:00

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-25T21:59:13-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '8e912434-40bd-4373-868b-c164c358d21c'	System	26 Feb 2021 03:03:00
User entered 'No (N)'	System	26 Feb 2021 03:03:00

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-02-25T21:59:19-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '8e912434-40bd-4373-868b-c164c358d21c'	System	26 Feb 2021 03:03:00
User entered '26 Feb 2021 02:59:19'	System	26 Feb 2021 03:03:00

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-01T14:34:57-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b6ea47b2-2363-4894-ac9c-5e631d2c8767'	System	01 Mar 2021 19:35:10
User entered 'No (N)'	System	01 Mar 2021 19:35:10

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-01T14:35:02-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b6ea47b2-2363-4894-ac9c-5e631d2c8767'	System	01 Mar 2021 19:35:10
User entered 'No (N)'	System	01 Mar 2021 19:35:10

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-01T14:35:07-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'b6ea47b2-2363-4894-ac9c-5e631d2c8767'	System	01 Mar 2021 19:35:10
User entered '01 Mar 2021 14:35:07'	System	01 Mar 2021 19:35:10

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-07T06:39:33-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'df248f53-6923-45e4-8aa5-51bbc5b7730c'	System	07 Mar 2021 11:39:48
User entered 'No (N)'	System	07 Mar 2021 11:39:48

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-07T06:39:40-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'df248f53-6923-45e4-8aa5-51bbc5b7730c'	System	07 Mar 2021 11:39:48
User entered 'No (N)'	System	07 Mar 2021 11:39:48

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-07T06:39:45-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'df248f53-6923-45e4-8aa5-51bbc5b7730c' User entered '07 Mar 2021 06:39:45'	System	07 Mar 2021 11:39:48
	System	07 Mar 2021 11:39:48

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-21T08:08:19-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'fa7e13fd-2018-4103-a33c-5c2b216ed82b'	System	21 Mar 2021 12:08:30
User entered 'No (N)'	System	21 Mar 2021 12:08:30

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-21T08:08:23-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'fa7e13fd-2018-4103-a33c-5c2b216ed82b'	System	21 Mar 2021 12:08:30
User entered 'No (N)'	System	21 Mar 2021 12:08:30

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-21T08:08:28-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'fa7e13fd-2018-4103-a33c-5c2b216ed82b' User entered '21 Mar 2021 08:08:28'	System	21 Mar 2021 12:08:30
	System	21 Mar 2021 12:08:30

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-30T18:15:36-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '793cb8a1-9081-4101-ac3e-c2160cf86322'	System	30 Mar 2021 22:15:51
User entered 'No (N)'	System	30 Mar 2021 22:15:51

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-30T18:15:41-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '793cb8a1-9081-4101-ac3e-c2160cf86322'	System	30 Mar 2021 22:15:51
User entered 'No (N)'	System	30 Mar 2021 22:15:51

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-30T18:15:45-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '793cb8a1-9081-4101-ac3e-c2160cf86322' User entered '30 Mar 2021 18:15:45'	System	30 Mar 2021 22:15:51
	System	30 Mar 2021 22:15:51

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-06T12:06:54-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'cfb489bb-74ba-44d0-a815-e6fdb072e68b' User entered 'No (N)'	System	22 Apr 2021 19:19:09
	System	22 Apr 2021 19:19:09

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-06T12:06:58-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'cfb489bb-74ba-44d0-a815-e6fdb072e68b' User entered 'No (N)'	System	22 Apr 2021 19:19:09

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-06T12:07:02-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'cfb489bb-74ba-44d0-a815-e6fdb072e68b'	System	22 Apr 2021 19:19:09
User entered '06 Apr 2021 12:07:02'	System	22 Apr 2021 19:19:09

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-22T15:19:07-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '558ff5a4-3964-4cc2-9af6-db2f6fd903f3'	System	22 Apr 2021 19:19:21
User entered 'No (N)'	System	22 Apr 2021 19:19:21

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-22T15:19:09-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '558ff5a4-3964-4cc2-9af6-db2f6fd903f3' User entered 'No (N)'	System	22 Apr 2021 19:19:21

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-22T15:19:14-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '558ff5a4-3964-4cc2-9af6-db2f6fd903f3'	System	22 Apr 2021 19:19:21
User entered '22 Apr 2021 15:19:14'	System	22 Apr 2021 19:19:21

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-28T18:10:42-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '68b17d67-44f2-4cad-a173-56c731a6d9d5' User entered 'No (N)'	System	28 Apr 2021 22:57:07
	System	28 Apr 2021 22:57:07

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-28T18:10:45-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '68b17d67-44f2-4cad-a173-56c731a6d9d5'	System	28 Apr 2021 22:57:07
User entered 'No (N)'	System	28 Apr 2021 22:57:07

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-04-28T18:10:49-04:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: '68b17d67-44f2-4cad-a173-56c731a6d9d5'	System	28 Apr 2021 22:57:07
User entered '28 Apr 2021 18:10:49'	System	28 Apr 2021 22:57:07

US3522128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-01T14:34:39-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd721e1af-904b-4985-b29d-2e740566e688'	System	01 Mar 2021 19:34:48
User entered 'No (N)'	System	01 Mar 2021 19:34:48

US3522128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:03:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:14:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7F90B204-01B3-4FEE-A388-DF9BBF29F6B5)', Time: '2021-03-01T14:34:45-05:00', User OID: 'PatientReportedOutcome (US3522128)', ODM File OID: 'd721e1af-904b-4985-b29d-2e740566e688'	System	01 Mar 2021 19:34:48
User entered '01 Mar 2021 14:34:45'	System	01 Mar 2021 19:34:48

US3522128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	10 Dec 2020 18:01:44
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 17:55:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 17:55:40
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	10 Dec 2020 17:55:40
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	10 Dec 2020 17:55:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	10 Dec 2020 17:55:29
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	10 Dec 2020 17:55:29
User entered empty; reason for change Data Entry Error	Yaman Ahmed (b) (4)	10 Dec 2020 17:55:29
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	10 Dec 2020 17:53:34
User entered 'No (N)'	Yaman Ahmed (b) (4)	10 Dec 2020 17:53:34
	(b) (4)	

US3522128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Yaman Ahmed (b) (4)	10 Dec 2020 17:53:34

US3522128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	10 Dec 2020 18:01:44
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4)	10 Dec 2020 17:53:34

US3522128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	Yaman Ahmed (b) (4)	10 Dec 2020 17:53:34

US3522128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	10 Dec 2020 17:55:48

US3522128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:31:24
User entered 'I'	System	10 Dec 2020 17:55:48

US3522128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	10 Dec 2020 18:03:45

US3522128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '10 Dec 2020'	Yaman Ahmed (b) (4)	10 Dec 2020 18:03:45

US3522128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	10 Dec 2020 18:03:45

US3522128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	Yaman Ahmed (b) (4)	10 Dec 2020 18:03:45

US3522128

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	10 Dec 2020 18:03:53

US3522128

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'I'	System	10 Dec 2020 18:03:53

US3522128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	09 Jan 2021 17:30:49

US3522128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '9 Jan 2021'	(b) (4) Alayna Wilder (b) (4)	09 Jan 2021 17:30:49

US3522128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Alayna Wilder (b) (4)	09 Jan 2021 17:30:49

US3522128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'number not in service'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 17:30:49

US3522128

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	08 Feb 2021 20:25:24

US3522128

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'I'	System	08 Feb 2021 20:25:24

US3522128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	08 Feb 2021 20:26:52

US3522128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 14:39:52
User entered '8 Feb 2021'	Alandra White (b) (4)	08 Feb 2021 20:26:52

US3522128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	09 Feb 2021 14:39:52
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alandra White (b) (4)	08 Feb 2021 20:26:52
	(b) (4)	

US3522128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:39:52
User entered 'Call attempted with no answer, left voicemail.' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	08 Feb 2021 20:27:42
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, or Covid-19 exposure.'	Alandra White (b) (4) (b) (4)	08 Feb 2021 20:26:52

US3522128

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:39:57

US3522128

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'I'	System	09 Feb 2021 14:39:57

US3522128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:49:26

US3522128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 08:02:42
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'pt unavailable any other day, deviation' (Site from System).	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:49:50
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Apr 2021 18:49:26
User entered '1 Apr 2021'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:49:26

US3522128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered 'Clinic (Clinic)'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:49:26

US3522128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'VISIT4'	System	01 Apr 2021 18:49:26

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '1 Apr 2021'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '14:20'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered '1 Apr 2021 14:20'	System	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '98.2' F	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered 'Other (Other)'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered 'temporal'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 07:26:23
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'reported as AE' (Site from System).	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:39
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Apr 2021 18:50:30
User entered '133'	Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'bpm'	System	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '26'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'breaths/min'	System	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '144'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'mmHg'	System	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '77'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'mmHg'	System	01 Apr 2021 18:50:30

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46

US3522128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46

US3522128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:51

US3522128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '1 Apr 2021'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:50:51

US3522128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:51:03

US3522128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '1 Apr 2021'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:51:03

US3522128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered '14:15' reason for change: Data Entry Error	(b) (4)	
	Alayna Wilder (b) (4)	01 Apr 2021 18:51:19
User entered '14:20'	(b) (4)	
	Alayna Wilder (b) (4)	01 Apr 2021 18:51:03
	(b) (4)	

US3522128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered '1 Apr 2021 14:15'	System	01 Apr 2021 18:51:19
User entered '1 Apr 2021 14:20'	System	01 Apr 2021 18:51:03

US3522128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	01 Apr 2021 18:51:26

US3522128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:51:46
User entered 'I'	System	01 Apr 2021 18:51:26

US3522128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	08 Apr 2021 19:56:25
	(b) (4)	

US3522128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 08:35:11
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Safety calls were not placed on the weekend' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:40:14
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Apr 2021 19:39:57
User entered '13 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:39:57
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:56:20
User entered '12 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:56:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
User entered '8 Apr 2021'	(b) (4) Yaman Ahmed (b) (4)	08 Apr 2021 19:56:25

US3522128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:39:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Apr 2021 19:39:57
reason for change: Data Entry Error		
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4)	08 Apr 2021 19:56:25
	(b) (4)	

US3522128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
	(b) (4)	
User entered 'See source note' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:39:57
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 19:56:20
	(b) (4), (b) (6)	12 Apr 2021 19:56:20
User entered '2nd attempt, LEFT A VOICEMAIL MESSAGE' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:56:20
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
	(b) (4)	
User entered 'left a voicemail message'	Yaman Ahmed (b) (4)	08 Apr 2021 19:56:25
	(b) (4)	

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:25

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '3 Feb 2021'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:25

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Clinic (Clinic)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:25

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 17:50:25

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '3 Feb 2021'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:03:48
User entered '0'	(b) (4) Sharon Mathys (b) (4)	16 Mar 2021 19:11:43
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 04:59:00

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:03:48
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Sharon Mathys (b) (4)	16 Mar 2021 19:11:43
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 04:59:00

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User closed query 'Per IRT, subject was unblinded on 03FEB2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:14:19
Query 'Per IRT, subject was unblinded on 03FEB2021. Please review and reconcile. ' answered with 'Accidental unblinding on 05 Jan 2021, no access to vaccine. dcr was made which reset the date.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	08 Apr 2021 16:53:16
User opened query 'Per IRT, subject was unblinded on 03FEB2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:22:01
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:25:37
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	05 Feb 2021 02:20:37
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Amendment 5 unblinding ' (Site from System).	Alandra White (b) (4) (b) (4)	03 Feb 2021 17:50:51
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	03 Feb 2021 17:50:40
User entered '5 Jan 2021'	Alandra White (b) (4) (b) (4)	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Placebo (Placebo)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Placebo (Placebo)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Placebo (Placebo)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '1'	System	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:03:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'I'	System	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered empty.	System	03 Feb 2021 18:53:39
DataPoint set to visible.	System	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered empty.	System	03 Feb 2021 18:53:39
DataPoint set to visible.	System	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User accepted default value 'Pre-Dose (PREDOSE)'	Alandra White (b) (4) (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '3 Feb 2021'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '12:14'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '3 Feb 2021 12:14'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '97.2' F	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Other (Other)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'temporal'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '95'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'bpm'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '16'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'breaths/min'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '113'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mmHg'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '69'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mmHg'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered missing code ND - Not Done.	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:03:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered empty.	System	03 Feb 2021 18:53:39
DataPoint set to visible.	System	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User accepted default value 'Post-Dose (POSTDOSE)'	Alandra White (b) (4) (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '3 Feb 2021'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '13:17'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '3 Feb 2021 13:17'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '97.2' F	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Other (Other)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'temporal'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '70'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'bpm'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '16'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'breaths/min'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '121'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mmHg'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '73'	Alandra White (b) (4)	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mmHg'	System	03 Feb 2021 18:53:39

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:02

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '3 Feb 2021'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:02

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mRNA-1273'	System	03 Feb 2021 17:52:20
DataPoint set to visible.	System	03 Feb 2021 17:50:40

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '3 Feb 2021'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '12:47'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '3 Feb 2021 12:47'	System	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'ONCE'	System	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 17:52:20

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:42

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '3 Feb 2021'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:42

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '12:40'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:42

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '3 Feb 2021 12:40'	System	03 Feb 2021 17:52:42

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:56

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '3 Feb 2021'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:56

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '12:35'	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:52:56

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '3 Feb 2021 12:35'	System	03 Feb 2021 17:52:56

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:52:04

US3522128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'I'	System	03 Feb 2021 18:52:04

US3522128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	Alandra White (b) (4)	10 Feb 2021 16:11:29

US3522128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '11 Feb 2021' reason for change: New Information	Yaman Ahmed (b) (4)	11 Feb 2021 21:53:04
User entered '10 Feb 2021'	Alandra White (b) (4)	10 Feb 2021 16:11:29

US3522128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	11 Feb 2021 21:53:04
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	Alandra White (b) (4)	10 Feb 2021 16:11:29
	(b) (4)	

US3522128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:19
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'Per DM CLR: Review specified comment, 2 DAY INJECTION SITE PAIN. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 05:33:29
Query 'Per DM CLR: Review specified comment, 2 DAY INJECTION SITE PAIN. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' answered with 'updated' (Site from DM).	Alandra White (b) (4) (b) (4)	02 Mar 2021 18:26:59
Signature has been broken.	Alandra White (b) (4) (b) (4)	02 Mar 2021 18:26:43
User entered 'NO ONGOING OR OTHER AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE' reason for change: New Information	Alandra White (b) (4) (b) (4)	02 Mar 2021 18:26:43
User opened query 'Per DM CLR: Review specified comment, 2 DAY INJECTION SITE PAIN. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:50:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:25:37
User entered '2 day injection site pain post OL Dose 1. No ongoing or other AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	11 Feb 2021 21:53:04
User entered 'Call attempted with no answer, left voicemail.'	Alandra White (b) (4) (b) (4)	10 Feb 2021 16:11:29

US3522128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	11 Feb 2021 21:53:10

US3522128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'I'	System	11 Feb 2021 21:53:10

US3522128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '1'	System	11 Feb 2021 21:53:10
DataPoint set to visible.	System	11 Feb 2021 21:53:10

US3522128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:32:53

US3522128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:32:53

US3522128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:32:53

US3522128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'OLD29'	System	03 Mar 2021 14:32:53

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '09:36'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '3 Mar 2021 09:36'	System	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '78'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'bpm'	System	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'breaths/min'	System	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '121'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mmHg'	System	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '69'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mmHg'	System	03 Mar 2021 14:38:03

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '10:10'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '3 Mar 2021 10:10'	System	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '78'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'bpm'	System	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'breaths/min'	System	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '118'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mmHg'	System	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '71'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mmHg'	System	03 Mar 2021 15:18:22

US3522128

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:10

US3522128

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:38:10

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'mRNA-1273'	System	03 Mar 2021 14:44:27
DataPoint set to visible.	System	11 Feb 2021 21:53:10

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '09:40'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered '3 Mar 2021 09:40'	System	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'ONCE'	System	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:03:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 14:44:27

US3522128

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:50:12

US3522128

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'I'	System	03 Mar 2021 14:50:12

US3522128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:16:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:17:05

US3522128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:16:29
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:17:05

US3522128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:16:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:17:05

US3522128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:03:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User closed query 'Per DM CLR: Review specified comment, HE FELT FATIGUED UNTIL THE NEXT DAY WHEN HE WOKE UP. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:13:08
Query 'Per DM CLR: Review specified comment, HE FELT FATIGUED UNTIL THE NEXT DAY WHEN HE WOKE UP. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' answered with 'Isolated symptom, does not meet AE criteria' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	16 Mar 2021 23:48:03
User opened query 'Per DM CLR: Review specified comment, HE FELT FATIGUED UNTIL THE NEXT DAY WHEN HE WOKE UP. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 13:34:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:16:29
User entered 'Pt states he felt fatigued until the next day when he woke up. Resolved around 6-8 hours after on 04 MAR 2021 according to pt. Denies any other issues at this time. Continued in source'	(b) (4), (b) (6)	10 Mar 2021 18:17:05

US3522128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:16:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:17:25

US3522128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:03:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:17
User entered 'I'	System	10 Mar 2021 18:17:25

US3522128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered 'Yes (Y)'	Alayna Wilder (b) (4)	01 Apr 2021 18:47:04
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered '1 Apr 2021'	Alayna Wilder (b) (4)	01 Apr 2021 18:47:04
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered 'Clinic (Clinic)'	Alayna Wilder (b) (4)	01 Apr 2021 18:47:04
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:03:33

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 18:47:04

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered 'Yes (Y)'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:14
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered '1 Apr 2021'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:14
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered '14:20'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:14
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User entered '1 Apr 2021 14:20'	System	01 Apr 2021 18:48:14

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:56:33
User entered '98.2' F	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:48:14

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered 'Other (Other)'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:14
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered 'temporal'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:14
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 07:25:48
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'reported as AE' (Site from System).	Alayna Wilder (b) (4)	01 Apr 2021 18:48:32
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Apr 2021 18:48:14
User entered '133'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:14

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 18:48:14

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:56:33
User entered '26'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:48:14

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 18:48:14

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered '144'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:14
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:48:14

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered '77'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:14
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:03:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:48:14

US3522128

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered 'Yes (Y)'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:46
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:03:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered '1 Apr 2021'	Alayna Wilder (b) (4)	01 Apr 2021 18:48:46
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered 'Yes (Y)'	Alayna Wilder (b) (4)	01 Apr 2021 18:49:09
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered '1 Apr 2021'	Alayna Wilder (b) (4)	01 Apr 2021 18:49:09
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:56:33
	(b) (4)	
User entered '14:15'	Alayna Wilder (b) (4)	01 Apr 2021 18:49:09
	(b) (4)	

US3522128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User entered '1 Apr 2021 14:15'	System	01 Apr 2021 18:49:09

US3522128

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:03:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:10
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:04:37
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:33:31

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'No (N)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'No (N)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Aug 2020 17:56:27
User entered '17:00' reason for change: Data Entry Error	Sharon Mathys (b) (4) (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) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'No (N)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	28 Aug 2020 17:56:11
User entered empty.	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
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: 10 Jun 2021 08:03:33

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Aug 2020 17:56:11
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 17:39:45
User entered empty.	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'No (N)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'None (NONE)'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered 'l'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered '0'	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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:	Sharon Mathys (b) (4)	28 Aug 2020 17:56:11
Data Entry Error	(b) (4)	
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)	28 Aug 2020 17:39:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (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) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:25:12
User entered empty.	Tyler Prentiss (b) (4) (b) (4)	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User entered '0'	System	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42
User entered '1'	System	28 Aug 2020 17:39:45

US3522128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:18:42

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
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)	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)	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)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
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) (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) (b) (4)	01 Oct 2020 15:07:20
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (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: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
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) (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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '20:47'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User entered '14 Aug 2020 20:47'	System	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '15 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '23:59'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User entered '15 Aug 2020 23:59'	System	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	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: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User entered '0'	System	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31
User entered '0'	System	04 Sep 2020 19:49:35

US3522128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:31

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4)	
	(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	System	02 Oct 2020 16:58:21
'USA-US131-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	02 Oct 2020 16:58:21

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4)	
	(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)	22 Oct 2020 17:37:42
	(b) (4)	
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
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 17:36:37
User entered 'ATRIAL Flutter WITH RAPID VENTRICULAR RESPONSE' reason for change:	Sharon Mathys (b) (4)	22 Oct 2020 17:35:43
	(b) (4)	
Data Entry Error		
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)	22 Oct 2020 17:34:51
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 17:34:35
DataPoint Un-verified.	Sharon Mathys (b) (4)	22 Oct 2020 17:34:17
	(b) (4)	
Coding entries removed.	Sharon Mathys (b) (4)	22 Oct 2020 17:34:17
	(b) (4)	
User entered 'Atrial FIBrillation EPISODE' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:34:17
	(b) (4)	
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)	03 Oct 2020 15:01:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 15:01:39
	(b) (4)	
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: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:26:12
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 01:36:41
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 01:36:41
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: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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) (b) (4)	11 Oct 2020 01:36:41
User entered '27 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4)	
	(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: 10 Jun 2021 08:03:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:04:49
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

US3522128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (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 'I'	(b) (4), (b) (6)	02 Oct 2020 15:35:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:26:19
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:37:04
User entered '0' reason for change: Data Entry Error	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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:26:22
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 01:37:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 01:37:13
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 05:44:22
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 05:42:03
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'PV Query: Please confirm if the subject was tested for COVID-19 during the hospitalization from 25 Sep 2020 through 27 Sep 2020 for the event of atrial flutter with rapid ventricular response. If so please provide positive or negative results with date(s) performed. If not tested (or unknown) please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:32:27
DataPoint Un-verified.	Sharon Mathys (b) (4)	18 Dec 2020 19:36:58
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 : METROPROLOL, DIGOXIN AND CHANGE IN HIS FUROSEMIDE MEDICATION. Was tested on 25Sep2020 in Hospital for SARS-COV-2 by PCR and tested negative.' reason for change: Data Entry Error	Sharon Mathys (b) (4)	18 Dec 2020 19:36:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if the subject was tested for COVID-19 during the hospitalization from 25 Sep 2020 through 27 Sep 2020 for the event of atrial flutter with rapid ventricular response. If so please provide positive or negative results with date(s) performed. If not tested (or unknown) please state so.' answered with 'Tested on 25 Sep 2020 for SARS-COV-2 by PCR and tested negative in hospital' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 19:36:16
User opened query 'PV Query: Please confirm if the subject was tested for COVID-19 during the hospitalization from 25 Sep 2020 through 27 Sep 2020 for the event of atrial flutter with rapid ventricular response. If so please provide positive or negative results with date(s) performed. If not tested (or unknown) please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:56:50
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) (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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
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
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 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 cardiomedastinal silhouette.' (Site from Safety).	Sharon Mathys (b) (4)	22 Oct 2020 17:56:10
DataPoint Un-verified.	Sharon Mathys (b) (4)	22 Oct 2020 17:54:50

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
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) (b) (4)	22 Oct 2020 17:54:50
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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 15:35:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
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). 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).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 03:01:39
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).	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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4)	
Query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'Was negative for COVID-19. Could not find on discharge or labs causative organism however antibiotics did help' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 05:18:42
User opened query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.'	Sharon Mathys (b) (4)	18 Dec 2020 19:30:06
User opened query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 06:44:59
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.	(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)	22 Oct 2020 23:31:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 18:00:31
Coding entries removed.	Sharon Mathys (b) (4)	22 Oct 2020 18:00:24
User entered 'Multifocal Pneumonia in both lungs' reason for change: New Information	(b) (4)	
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.	Sharon Mathys (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.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Oct 2020 05:18:18
Data point term sent to Coder	(b) (4)	
User entered 'PULMONARY EDEMA in both lungs' reason for change: New Information	System	11 Oct 2020 02:08:32
Data point term sent to Coder	Sharon Mathys (b) (4)	11 Oct 2020 02:08:23
User entered 'Pulmonary Edema'	(b) (4)	
	System	11 Oct 2020 02:07:32
	Sharon Mathys (b) (4)	11 Oct 2020 02:07:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'PV Query: Start date was updated to 14 OCT 2020; which is six days after symptoms began and the subject was hospitalized. Please clarify the rationale for updating the start date.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 14:06:31
Query 'PV Query: Start date was updated to 14 OCT 2020; which is six days after symptoms began and the subject was hospitalized. Please clarify the rationale for updating the start date.' answered with 'Was admitted for SOB on 08 Oct 2020, so that was the start of symptoms that lead to the diagnosis of multifocal pneumonia ' (Site from Safety).	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 18:33:11
User entered '8 Oct 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 18:32:21
User opened query 'PV Query: Start date was updated to 14 OCT 2020; which is six days after symptoms began and the subject was hospitalized. Please clarify the rationale for updating the start date.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:51:19
DataPoint Un-verified.	(b) (4), (b) (6)	25 Nov 2020 18:01:15
User entered '14 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 18:01:15
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: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:13:46
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	20 Oct 2020 14:47:33
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:01:15
User entered '18 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 18:01:15
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) (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) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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)

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[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: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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) (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 'I'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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) (b) (4)	20 Oct 2020 14:46:23
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: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sharon Mathys (b) (4)	11 Oct 2020 02:07:17

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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 'I'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

US3522128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 02:21:56
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'please clarify query, it does not make sense' (Site from DM).	Alandra White (b) (4) (b) (4)	03 Feb 2021 18:30:53
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	15 Jan 2021 18:19:23
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Jan 2021 18:19:23
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:10:02
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) (b) (4)	22 Oct 2020 18:02:18
User entered '1'	Sharon Mathys (b) (4) (b) (4)	11 Oct 2020 02:07:17

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'Per DM CLR: Narrative = NOTED TO BE IN AFIB WHILE IN THE ED (timeframe within this hospitalization period). However, please review and verify if this qualifies to be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 05:13:56
Query 'Per DM CLR: Narrative = NOTED TO BE IN AFIB WHILE IN THE ED (timeframe within this hospitalization period). However, please review and verify if this qualifies to be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'participant has known history of a.fib, see medical history ' (Site from DM).	Alandra White (b) (4) (b) (4)	22 Feb 2021 13:45:25
User opened query 'Per DM CLR: Narrative = NOTED TO BE IN AFIB WHILE IN THE ED (timeframe within this hospitalization period). However, please review and verify if this qualifies to be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:57:58
User closed query 'Per DM CLR: SAE Narrative = HIS BNP WAS 295. However, this is not recorded in the ConProc eCRF (i.e., Blood work up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 02:21:22
User closed query 'Per DM CLR: SAE Narrative = HIS INR WAS ELEVATED. However, this is not recorded in the ConProc eCRF (i.e., Blood work up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 02:21:17
Query 'Per DM CLR: SAE Narrative = HIS BNP WAS 295. However, this is not recorded in the ConProc eCRF (i.e., Blood work up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Alandra White (b) (4) (b) (4)	03 Feb 2021 18:43:32

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = HIS INR WAS ELEVATED. However, this is not recorded in the ConProc eCRF (i.e., Blood work up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Alandra White (b) (4)	03 Feb 2021 18:43:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[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): PT 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 541. 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	Alandra White (b) (4) (b) (4)	03 Feb 2021 18:43:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
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		
User closed query 'Per DM CLR: SAE Narrative = ON CPAP WITH 10L NC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 06:17:22
Query 'Per DM CLR: SAE Narrative = ON CPAP WITH 10L NC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'See heated high flow nasal cannula' (Site from DM).	Sharon Mathys (b) (4)	15 Jan 2021 18:14:32
User opened query 'Per DM CLR: SAE Narrative = HIS BNP WAS 295. However, this is not recorded in the ConProc eCRF (i.e., Blood work up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:09:55
User opened query 'Per DM CLR: SAE Narrative = HIS INR WAS ELEVATED. However, this is not recorded in the ConProc eCRF (i.e., Blood work up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:09:50
User opened query 'Per DM CLR: SAE Narrative = ON CPAP WITH 10L NC. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 01:09:29
User closed query 'PV Query Urgent: Please remove subject PHI from the narrative.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 13:06:31
Query 'PV Query Urgent: Please remove subject PHI from the narrative.' answered with 'Removed. Please check' (Site from Safety).	Sharon Mathys (b) (4)	14 Dec 2020 17:06:53
DataPoint Un-verified.	Sharon Mathys (b) (4)	14 Dec 2020 17:06:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

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[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): Pt 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 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	Sharon Mathys (b) (4) (b) (4)	14 Dec 2020 17:06:08

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Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
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		
User closed query 'Per DM CLR: Narrative indicates that the subject had CT Scan, HHFNC, Sputum Culture . However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:32:11
User opened query 'PV Query Urgent: Please remove subject PHI from the narrative.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:51:11
Query 'Per DM CLR: Narrative indicates that the subject had CT Scan, HHFNC, Sputum Culture . However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4)	11 Dec 2020 18:33:38
User opened query 'Per DM CLR: Narrative indicates that the subject had CT Scan, HHFNC, Sputum Culture . However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 13:49:57
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

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:03:33

[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

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[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

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Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User closed query 'Per DM CLR: Please specify the location of Gout. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 05:33:51
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 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:43:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:43:57
Data point term sent to Coder	System	10 Dec 2020 18:40:42
User entered 'GOUT FLAIR (left knee and right elbow)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 18:40:03
Data point term sent to Coder	System	10 Dec 2020 18:31:33
Query 'Per DM CLR: Please specify the location of Gout. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 18:30:47
Coding entries removed.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 18:30:40
User entered 'GOUT FLAIR (Chronic Gout of Multiple Sites)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 18:30:40
User opened query 'Per DM CLR: Please specify the location of Gout. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 13:49:33
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

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4)	22 Oct 2020 21:16:32
User entered 'Gout Flair'	(b) (4) System	22 Oct 2020 18:53:24
	Sharon Mathys (b) (4)	22 Oct 2020 18:52:39
	(b) (4)	

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '10 Oct 2020'	(b) (4) Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User entered empty.	System	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '11 Oct 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User entered empty.	System	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Not Related (NOT RELATED)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
User entered empty.	(b) (4) Sharon Mathys (b) (4)	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:33:58
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: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User entered '0'	System	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36
User entered 'I'	System	22 Oct 2020 18:52:39

US3522128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:36

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 18:53:43
User entered 'USA-US131-2021-mRNA-1273-P301000015'	System	02 Apr 2021 18:53:36
Un-reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 18:53:36
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 18:53:36
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 18:52:44
User entered 'USA-US131-2020-mRNA-1273-P301000008'	(b) (4), (b) (6)	02 Apr 2021 18:52:40

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:01:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:01:41
User closed query '. PV Query: Kindly confirm if the SAE term should be revised to "worsening of atrial fibrillation" ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 10:33:12
Query '. PV Query: Kindly confirm if the SAE term should be revised to "worsening of atrial fibrillation" ' answered with 'It's documented as recurrent/persistent Epic source U OF M admission note' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:39:57
Data point term sent to Coder	System	12 Apr 2021 19:39:07
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 19:39:04
User entered 'Recurrent paroxysmal Atrial Fibrillation status post multiple failed ablations and medical/direct cardioversions' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:39:04
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)	09 Apr 2021 18:47:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:47:46
Data point term sent to Coder	System	09 Apr 2021 18:47:06
Coding entries removed.	Alandra White (b) (4) (b) (4)	09 Apr 2021 18:47:00
User entered 'EPISODE of AFIB' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	09 Apr 2021 18:47:00
User opened query '. PV Query: Kindly confirm if the SAE term should be revised to "worsening of atrial fibrillation" ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:31:27
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: AFib - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 18:47:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 18:47:39
Data point term sent to Coder	System	01 Apr 2021 18:47:03

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Afib Episode'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Apr 2021'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

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

Audit	User	Time (GMT)
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	01 Apr 2021 19:00:37
User entered empty; reason for change Data Entry Error	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 19:00:37
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	01 Apr 2021 18:46:04
User entered '14:00'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:00:37
User entered '1 Apr 2021 14:00'	System	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 05:48:59
User entered empty.	Alayna Wilder (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 05:49:27
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:30:39
User entered empty.	System	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:03:36
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' answered with 'updated' (Site from Safety).	Alayna Wilder (b) (4)	02 Apr 2021 15:07:31
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 20:52:21
User entered 'Yes (Y)'	Alayna Wilder (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Apr 2021 13:03:27
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 by data change (Site from System).		09 Apr 2021 13:03:27
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	09 Apr 2021 12:58:49
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)	06 Apr 2021 08:03:02
User closed query 'Per CDM: Query response noted. However, please review and confirm if 'Requires inpatient or prolongation of existing Hospitalization' can be checked/ticked. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 05:53:59
Query 'Per CDM: Query response noted. However, please review and confirm if 'Requires inpatient or prolongation of existing Hospitalization' can be checked/ticked. Thank you. ' answered with 'checked the box' (Site from DM).	Sharon Mathys (b) (4)	05 Apr 2021 12:50:30
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not discharged yet' (Site from System).	Sharon Mathys (b) (4)	05 Apr 2021 12:50:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Apr 2021 12:50:07

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	05 Apr 2021 12:50:07
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	03 Apr 2021 04:15:46
User opened query 'Per CDM: Query response noted. However, please review and confirm if 'Requires inpatient or prolongation of existing Hospitalization' can be checked/ticked. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:15:43
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'updated admission dates as well as narrative' (Site from System).	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 15:11:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Apr 2021 15:08:56
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Apr 2021 19:00:37
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	01 Apr 2021 19:00:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Apr 2021 18:46:04
User entered '0'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Apr 2021' reason for change: Data Entry Error	Alayna Wilder (b) (4)	02 Apr 2021 15:08:56
User entered empty.	Alayna Wilder (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 05:51:02
User entered '04 Apr 2021' reason for change: New Information	Sharon Mathys (b) (4)	09 Apr 2021 12:58:49
User entered empty.	Alayna Wilder (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Sharon Mathys (b) (4)	09 Apr 2021 13:03:27
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	01 Apr 2021 19:00:37
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		01 Apr 2021 19:00:37
User entered empty; reason for change Data Entry Error	Alayna Wilder (b) (4)	01 Apr 2021 19:00:37
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	01 Apr 2021 18:46:04
User entered 'Unknown (UNK)'	Alayna Wilder (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User entered 'I'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [date], then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 10:33:20
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [date], then event occurred). ' answered with 'Please clarify? Timeline shows that during unblinding phase both doses had already been administered. This was noticed on one month follow up visit after second dose leading for the action taken to be not applicable.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	12 Apr 2021 12:18:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	09 Apr 2021 18:49:01
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [date], then event occurred). ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:32:49
User entered 'None (NONE)'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

None

Audit	User	Time (GMT)
User entered 'I'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 05:47:46
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 19:00:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 19:00:37
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Alayna Wilder (b) (4)	01 Apr 2021 19:00:37
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 18:46:04
User entered empty.	Alayna Wilder (b) (4)	01 Apr 2021 18:46:04

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[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. ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 05:49:41
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 05:47:43
User closed query 'PV Query: The subject had a history of AFIB, kindly confirm the details including date. ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 12:42:24
Query 'PV Query: The subject had a history of AFIB, kindly confirm the details including date. ' answered with 'Per Epic source note 15-AUG-2013 Michigan medicine, cardiology, history of persistent atrial fibrillation with a diagnosis of atrial fibrillation for over five years. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 19:52:08
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)	09 Apr 2021 16:33:11
Query ' . PV Query: Kindly confirm if the SAE term should be revised to "worsening of atrial fibrillation" ' canceled (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:31:10
User opened query ' . PV Query: Kindly confirm if the SAE term should be revised to "worsening of atrial fibrillation" ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:30:58
User opened query 'PV Query: The subject had a history of AFIB, kindly confirm the details including date. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:30:51

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:30:20

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WHEN ASKED ABOUT MED HX AND CURRENT HEALTH STATUS PT REPORTED "I FELT MYSELF GO BACK INTO A-FIB ABOUT A WEEK AGO", HE IS NOTICEABLY SHORTNESS OF BREATH WITH ACTIVITY, AND REPORTS BEING SLIGHTLY LIGHTHEADED WHEN HE CHANGES FROM SITTING TO STANDING TOO QUICKLY. HE HAD ALREADY CONTACTED HIS CARDIOLOGIST AND HAS APPOINTMENT SET UP FOR 4/7. HOWEVER, UPON ASSESSING VITALS IT WAS FOUND THAT HIS HR WAS FLUCTUATING BETWEEN 121-135. APPLE WATCH ELECTROCARDIOGRAM FEATURE CONFIRMED MY FINDINGS WITH NOTICEABLE IRREGULARITIES. PT WAS ADVISED TO CALL CARDIOLOGIST BEFORE LEAVING CLINIC. DR. KILGORE, STUDY PHYSICIAN, WAS ALSO NOTIFIED AND INTERVIEWED PT. AFTER SPEAKING WITH CARDIOLOGY PA AND (b) (6), IT WAS DETERMINED THAT PT SHOULD GO TO NORTHVILLE URGENT CARE FOR AN ELECTROCARDIOGRAM, ORDERED BY (b) (6) (b) (6) OFFICE. I SUGGESTED MAYBE ER WOULD BE BETTER OPTION DUE TO SYMPTOMS AND RATE AS URGENT CARE WOULD MORE THAN LIKELY TRANSFER TO ER. PATIENT (b) (6) AND WILL HAVE WIFE DRIVE HIM TO EITHER URGENT CARE OR ER. PATIENT AOX4 AND REPORTS BEING CAPABLE OF GETTING HIMSELF TO ER VIA PRIVATE AUTO. PT HAS HISTORY OF MULTIPLE ABLATIONS AND CARDIOVERTS. EDUCATION PROVIDED, PT AWARE THAT HE SHOULD BE MONITORING RATE AS WELL AS RHYTHM AND TO REPORT SYMPTOMS IN THEIR ENTIRETY TO CARDIOLOGIST. SPOKE WITH PATIENT 4/2 AND HE REPORTS THAT HE DID GO TO ER, EKG showed afib RVR, THEY ADMITTED HIM FOR CARDIOLOGY CONSULT,	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 15:27:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
POSSIBLE ABLATION, WILL UPDATE WHEN POSSIBLE.' reason for change: Data Entry Error		

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WHEN ASKED ABOUT MED HX AND CURRENT HEALTH STATUS PT REPORTED "I FELT MYSELF GO BACK INTO A-FIB ABOUT A WEEK AGO", HE IS NOTICEABLY SHORTNESS OF BREATH WITH ACTIVITY, AND REPORTS BEING SLIGHTLY LIGHTHEADED WHEN HE CHANGES FROM SITTING TO STANDING TOO QUICKLY. HE HAD ALREADY CONTACTED HIS CARDIOLOGIST AND HAS APPOINTMENT SET UP FOR 4/7. HOWEVER, UPON ASSESSING VITALS IT WAS FOUND THAT HIS HR WAS FLUCTUATING BETWEEN 121-135. APPLE WATCH ELECTROCARDIOGRAM FEATURE CONFIRMED MY FINDINGS WITH NOTICEABLE IRREGULARITIES. PT WAS ADVISED TO CALL CARDIOLOGIST BEFORE LEAVING CLINIC. DR. KILGORE, STUDY PHYSICIAN, WAS ALSO NOTIFIED AND INTERVIEWED PT. AFTER SPEAKING WITH CARDIOLOGY PA AND (b) (6), IT WAS DETERMINED THAT PT SHOULD GO TO NORTHVILLE URGENT CARE FOR AN ELECTROCARDIOGRAM, ORDERED BY (b) (6) (b) (6) OFFICE. I SUGGESTED MAYBE ER WOULD BE BETTER OPTION DUE TO SYMPTOMS AND RATE AS URGENT CARE WOULD MORE THAN LIKELY TRANSFER TO ER. PATIENT (b) (6) AND WILL HAVE WIFE DRIVE HIM TO EITHER URGENT CARE OR ER. PATIENT AOX4 AND REPORTS BEING CAPABLE OF GETTING HIMSELF TO ER VIA PRIVATE AUTO. PT HAS HISTORY OF MULTIPLE ABLATIONS AND CARDIOVERTS. EDUCATION PROVIDED, PT AWARE THAT HE SHOULD BE MONITORING RATE AS WELL AS RHYTHM AND TO REPORT SYMPTOMS IN THEIR ENTIRETY TO CARDIOLOGIST. Spoke with patient 4/2 and he reports that he did go to ER and they admitted him for cardiology consult, possible ablation, will update when possible.' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 15:08:56

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'When asked about med hx and current health status pt reported "I felt myself go back into a-fib about a week ago", he is noticeably shortness of breath with activity, and reports being slightly lightheaded when he changes from sitting to standing too quickly. He had already contacted his cardiologist and has appointment set up for 4/7. However, upon assessing vitals it was found that his HR was fluctuating between 121-135. Apple watch electrocardiogram feature confirmed my findings with noticeable irregularities. Pt was advised to call cardiologist before leaving clinic. Dr. Kilgore, study physician, was also notified and interviewed pt. After speaking with cardiology PA and (b) (6), it was determined that pt should go to Northville urgent care for an electrocardiogram, ordered by (b) (6) office. I suggested maybe ER would be better option due to symptoms and rate as urgent care would more than likely transfer to ER. Patient (b) (6) and will have wife drive him to either urgent care or ER. Patient AOx4 and reports being capable of getting himself to ER via private auto. Pt has history of multiple ablations and cardioverts. Education provided, pt aware that he should be monitoring rate as well as rhythm and to report symptoms in their entirety to cardiologist.'	Alayna Wilder (b) (4) (b) (4)	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 18:46:04

US3522128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:03:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 18:46:04

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:03:33

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:10
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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) (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) (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) (b) (4)	14 Aug 2020 13:58:29

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'l'	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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 18:20:43
User entered 'Yes (Y)'	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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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.	(b) (4) 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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:14
User entered 'No (N)'	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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:16
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: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
DataPoint Un-verified.	Alandra White (b) (4)	03 Feb 2021 17:57:13
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Alandra White (b) (4)	03 Feb 2021 17:57:13
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'once daily (QD)'	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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'I'	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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:10
User entered 'Yes (Y)'	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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Feb 2021 17:57:13
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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 09:08:01
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'updated in mh' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 15:05:35
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 02:06:21
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:08
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 17:58:12
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Alandra White (b) (4)	03 Feb 2021 17:58:12
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
	(b) (4)	
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
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 17:58:12
	(b) (4)	
User entered '14 Oct 2020' reason for change: Data Entry Error	Alandra White (b) (4)	03 Feb 2021 17:58:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:08
	(b) (4)	
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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Aug 2020 14:29:18

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:23
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered 'Oral (ORAL)'	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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:05
User entered 'I'	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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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	System	22 Oct 2020 17:39:48
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	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	System	05 Oct 2020 17:45:29
Coding entries removed.	(b) (4), (b) (6)	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	System	14 Aug 2020 14:31:24
User entered 'Metoprolol'	Kristin Eis (b) (4) (b) (4)	14 Aug 2020 14:31:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (b) (4)	14 Aug 2020 14:31:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:05:31
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:00:34
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:59:26
DataPoint Un-verified.	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:59:19
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4) Alandra White (b) (4)	03 Feb 2021 17:59:19
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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered 'l'	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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:05:31
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:00:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:00:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	22 Oct 2020 17:39:05
User entered 'Yes (Y)'	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: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '26 Sep 2017' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:05:31
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:00:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:00:34
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.	(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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User entered '1'	System	03 Feb 2021 18:05:31
User entered '2'	System	03 Feb 2021 18:00:34
User entered '1'	System	03 Feb 2021 17:59:26
User entered '2'	System	03 Feb 2021 17:59:19
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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	System	05 Oct 2020 17:45:29
Coding entries removed.	(b) (4), (b) (6)	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	System	14 Aug 2020 14:32:26
User entered 'FUROSAMIDE'	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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered '40'	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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'l'	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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:46:24
User entered 'Yes (Y)'	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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:51:00
User entered 'No (N)'	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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:43
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:50:59
User entered 'No (N)'	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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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).	(b) (4), (b) (6)	07 Oct 2020 10:11:34
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 17:45:35
User entered 'Afib' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:45:31
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 05:45:11
User entered 'bp'	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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (b) (4)	14 Aug 2020 14:34:13
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) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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'	(b) (4) 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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	14 Aug 2020 14:33:28

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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.	(b) (4) Coder Import (b) (4) (b) (4)	04 Feb 2021 11:13:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 11:13:54
Data point term sent to Coder DataPoint Un-verified.	System Alandra White (b) (4) (b) (4)	03 Feb 2021 18:46:43 03 Feb 2021 18:46:13
Coding entries removed.	Alandra White (b) (4) (b) (4)	03 Feb 2021 18:46:13
User entered 'METOPROLOL' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	03 Feb 2021 18:46:13
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:53
User entered '0'	Sharon Mathys (b) (4)	22 Oct 2020 17:42:49

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:16
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:36:17
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 19:36:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:36:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	22 Oct 2020 17:47:07
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
	(b) (4)	
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		13 Apr 2021 19:36:17
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	13 Apr 2021 19:36:10
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 19:36:10
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 19:36:10
	(b) (4), (b) (6)	
User entered '07 Apr 2021' reason for change: Data Entry Error		13 Apr 2021 19:36:10
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:51
User entered empty.	Sharon Mathys (b) (4)	22 Oct 2020 17:47:07
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered empty.	Sharon Mathys (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered '0'	Sharon Mathys (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:50:48
User entered 'No (N)'	Sharon Mathys (b) (4)	22 Oct 2020 17:52:26

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:38
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	22 Oct 2020 18:09:50

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered '0'	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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered '09 Oct 2020'	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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:21
User entered 'No (N)'	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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:45
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:27
User entered '0'	Sharon Mathys (b) (4)	22 Oct 2020 18:13:21

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:49
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User entered 'I'	System	22 Oct 2020 18:15:16

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
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: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	22 Oct 2020 18:17:01

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:58
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: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (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) (b) (4)	22 Oct 2020 18:18:10

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:39
User entered '14 Oct 2020'	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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:03
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered empty.	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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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'	(b) (4) 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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Un-verified.	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:03:48
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Alandra White (b) (4)	03 Feb 2021 18:03:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	22 Oct 2020 18:22:42
	(b) (4)	

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	03 Feb 2021 18:04:07
User entered '16 Oct 2020' reason for change: Data Entry Error	Alandra White (b) (4)	03 Feb 2021 18:04:07
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	03 Feb 2021 18:03:58
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	03 Feb 2021 18:03:58
User entered 'UN Oct 2020' reason for change: Data Entry Error	Alandra White (b) (4)	03 Feb 2021 18:03:58
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	03 Feb 2021 18:03:48
DataPoint Un-verified.	Alandra White (b) (4)	03 Feb 2021 18:03:48
User entered 'un UNK 2020' reason for change: Data Entry Error	Alandra White (b) (4)	03 Feb 2021 18:03:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:19:42
User entered empty.	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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:14
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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'	(b) (4) 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: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'Subcutaneous (SUBCUTANEOUS)'	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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
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: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:57:18
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: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: GLUCOCORTICOIDS, 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: GLUCOCORTICOIDS, 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: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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) (b) (4)	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[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: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 18:28:17

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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.	(b) (4) Coder Import (b) (4)	28 Jan 2021 18:30:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 18:30:20
Data point term sent to Coder	System	28 Jan 2021 18:29:34
Coding entries removed.	Alayna Wilder (b) (4)	28 Jan 2021 18:28:34
Coding entries removed.	(b) (4)	
	Alayna Wilder (b) (4)	28 Jan 2021 18:28:34
	(b) (4)	
User entered 'ELIQUIS' reason for change: Data Entry Error	Alayna Wilder (b) (4)	28 Jan 2021 18:28:34
	(b) (4)	
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)	25 Nov 2020 18:55:25
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 18:55:25
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 18:06:54
User entered 'elliquis'	(b) (4), (b) (6)	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 07:06:05
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded ' answered with 'updated' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	28 Jan 2021 18:28:45
User entered 'a-fib' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	28 Jan 2021 18:28:34
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:39:37
User entered 'blood thinner'	(b) (4), (b) (6)	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '5'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) (b) (4), (b) (6) 	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '18 Oct 2020'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) 	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) 	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 18:06:24

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
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.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:11:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:11:44
Data point term sent to Coder	System	12 Apr 2021 19:50:27
User entered 'diltiazem'	(b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'atrial fibrillation'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '180'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'once at night'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:49:31

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:15:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:15:00
Data point term sent to Coder	System	12 Apr 2021 19:53:42
User entered 'AMIODARONE'	(b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'ATRIAL FIBRILLATION'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '400'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '04 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 19:53:23

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:16:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:16:00
Data point term sent to Coder	System	12 Apr 2021 19:54:43
User entered 'AMIODARONE'	(b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'ATRIAL FIBRILLATION'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '200'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 19:54:20

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Apr 2021 19:54:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 19:54:19
Data point term sent to Coder	System	13 Apr 2021 19:37:16
User entered 'furosemide'	(b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Congestive heart failure'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '40'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 19:37:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 19:37:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:37:17
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 19:37:12
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 19:37:12

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: K-TAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 09:01:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 09:01:50
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	14 Apr 2021 22:31:31
Data point term sent to Coder	System	13 Apr 2021 19:56:56
User entered 'potaassium chloride (K-TAB)'	(b) (4), (b) (6) (b) (4)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'chronic systolic heart failure'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '20'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'mEq'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '24 Apr 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 19:56:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 19:56:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 19:56:42
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 19:56:38
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:03:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 19:56:38

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:03:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:10
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
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: 10 Jun 2021 08:03:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '29 Aug 2020'	Kristin Eis (b) (4)	11 Sep 2020 17:02:24
	(b) (4)	

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered 'cardioversion'	Kristin Eis (b) (4)	11 Sep 2020 17:02:24
	(b) (4)	

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered 'Medical History (MH)'	Kristin Eis (b) (4)	11 Sep 2020 17:02:24
	(b) (4)	

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered empty.	Kristin Eis (b) (4)	11 Sep 2020 17:02:24
	(b) (4)	

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:00:18
User entered '12 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	25 Nov 2020 18:00:18
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: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '08 Oct 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:14:40

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'XRay CHEST PORTABLE 1 VIEW'	(b) (4)	
reason for change: Data Entry Error	Sharon Mathys (b) (4)	11 Dec 2020 18:15:42
User entered 'XR CHEST PORTABLE 1 VIEW'	(b) (4)	
reason for change: Data Entry Error	Sharon Mathys (b) (4)	11 Dec 2020 18:15:36
User entered 'XR Chest Portable 1 View Stat'	(b) (4)	
	Sharon Mathys (b) (4)	11 Dec 2020 18:14:40
	(b) (4)	

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	11 Dec 2020 18:15:23
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	11 Dec 2020 18:14:40

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:14:40

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '08 Oct 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:15:11

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Electrophysiology Study'	Sharon Mathys (b) (4)	11 Dec 2020 18:15:11

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	11 Dec 2020 18:15:17
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4)	
	Sharon Mathys (b) (4)	11 Dec 2020 18:15:11
	(b) (4)	

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:15:11

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '08 Oct 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:16:12

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Emergency Department Ultrasound Cardiac'	Sharon Mathys (b) (4)	11 Dec 2020 18:16:12

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4)	11 Dec 2020 18:16:12

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:16:12

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	11 Dec 2020 18:16:37
User entered '08 Nov 2020'	(b) (4)	
	Sharon Mathys (b) (4)	11 Dec 2020 18:16:32
	(b) (4)	

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'CT Chest'	Sharon Mathys (b) (4)	11 Dec 2020 18:16:32

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4)	11 Dec 2020 18:16:32

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:16:32

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '12 Oct 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:17:18

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'EKG 12 lead'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:17:18

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4)	11 Dec 2020 18:17:18

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:17:18

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '09 Oct 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:32:05

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Heated High Flow Nasal Cannula'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:32:05

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4)	11 Dec 2020 18:32:05

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:32:05

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '09 Oct 2020'	(b) (4) Sharon Mathys (b) (4)	11 Dec 2020 18:32:33

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Blood Culture'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:32:33

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:32:33

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:32:33

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '09 Oct 2020'	(b) (4) Sharon Mathys (b) (4)	11 Dec 2020 18:32:49

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Sputum Culture'	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:32:49

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4)	11 Dec 2020 18:32:49

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	11 Dec 2020 18:32:49

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '8 Oct 2020'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:44:33

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Protime with INR (blood draw)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:44:33

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)'	Alandra White (b) (4)	03 Feb 2021 18:44:33

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:44:33

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:03:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:31
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '8 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:45:05
User entered '3 Feb 2021'	(b) (4)	
	Alandra White (b) (4)	03 Feb 2021 18:44:55
	(b) (4)	

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:03:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:31
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Cardiac profile (blood draw)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:44:55

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:03:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:31
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered 'Adverse Event (AE)'	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:44:55

US3522128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:03:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:30:31
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered empty.	(b) (4) Alandra White (b) (4)	03 Feb 2021 18:44:55

US3522128

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:52:50
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:04:33
User entered 'I'	(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: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '12/Oct/2020 15:53'	(b) (4) System	12 Oct 2020 15:53:02

US3522128

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

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:53:36
User entered 'I'	(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: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '21/Oct/2020 16:53'	(b) (4) System	21 Oct 2020 16:53:55

US3522128

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

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:23:29
User entered 'I'	(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: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '23/Oct/2020 14:23'	(b) (4) System	23 Oct 2020 14:23:46

US3522128

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

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:35:16
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 14:23:46

US3522128

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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 (5)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '30/Nov/2020 13:35'	(b) (4) System	30 Nov 2020 18:35:30

US3522128

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

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:10
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 18:35:30

US3522128

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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 (6)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '11/Dec/2020 08:08'	(b) (4) System	11 Dec 2020 14:09:00

US3522128

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

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 13:07:10
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 14:09:00

US3522128

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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 (7)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '15/Dec/2020 13:07'	(b) (4) System	15 Dec 2020 13:07:21

US3522128

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

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:33:38
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 13:07:21

US3522128

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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 (8)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '21/Dec/2020 13:33'	(b) (4) System	21 Dec 2020 13:33:49

US3522128

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

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:28:26
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 13:33:49

US3522128

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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 (9)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '19/Jan/2021 18:28'	(b) (4) System	19 Jan 2021 18:28:38

US3522128

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

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:20:08
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 18:28:38

US3522128

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

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
DataPoint Verified.	(b) (4) (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: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4) (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: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
	(b) (4)	
User entered '10'	System	04 Feb 2021 15:20:04
User entered '9'	System	19 Jan 2021 18:28:38
User entered '8'	System	21 Dec 2020 13:33:49
User entered '7'	System	15 Dec 2020 13:07:21
User entered '6'	System	11 Dec 2020 14:09:00
User entered '5'	System	30 Nov 2020 18:35:30
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 (10)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
User entered '04/Feb/2021 10:20'	(b) (4) System	04 Feb 2021 15:20:04

US3522128

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

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:25:37
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 15:20:08
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 15:20:04

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'USA-US131-2021-MRNA-1273-P301000015'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:20:18
Un-reviewed for Safety.	System	05 Apr 2021 12:50:07
Signature has been broken.	System	05 Apr 2021 12:50:07
User entered 'Yes (Y)'	System	05 Apr 2021 12:50:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Paul'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Kilgore'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) ,	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) '	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'MI'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
User entered 'US'	(b) (4) System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 10:33:53
User entered '3'	System	12 Apr 2021 15:39:01
User entered '2'	System	05 Apr 2021 15:20:31
User entered '1'	System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'USA-US131-2021-MRNA-1273-P301000015'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:20:18
Un-reviewed for Safety.	System	05 Apr 2021 12:50:07
Signature has been broken.	System	05 Apr 2021 12:50:07
User entered 'Yes (Y)'	System	05 Apr 2021 12:50:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Paul'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Kilgore'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) ,	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) '	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'MI'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
User entered 'US'	(b) (4) System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 10:33:53
User entered '3'	System	12 Apr 2021 15:39:01
User entered '2'	System	05 Apr 2021 15:20:31
User entered '1'	System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
User entered '02/Apr/2021 14:54'	(b) (4) System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:03:33

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)	05 Apr 2021 15:20:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'USA-US131-2021-MRNA-1273-P301000015'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:20:18
Un-reviewed for Safety.	System	05 Apr 2021 12:50:07
Signature has been broken.	System	05 Apr 2021 12:50:07
User entered 'Yes (Y)'	System	05 Apr 2021 12:50:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Paul'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Kilgore'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) ,	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) '	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'MI'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
User entered 'US'	(b) (4) System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 10:33:53
User entered '3'	System	12 Apr 2021 15:39:01
User entered '2'	System	05 Apr 2021 15:20:31
User entered '1'	System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
User entered '05/Apr/2021 11:20'	(b) (4) System	05 Apr 2021 15:20:31

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:03:33

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 Apr 2021 15:38:47
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:20:31

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'USA-US131-2021-MRNA-1273-P301000015'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:20:18
Un-reviewed for Safety.	System	05 Apr 2021 12:50:07
Signature has been broken.	System	05 Apr 2021 12:50:07
User entered 'Yes (Y)'	System	05 Apr 2021 12:50:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Paul'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Kilgore'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) ,	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) '	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'MI'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
User entered 'US'	(b) (4) System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 10:33:53
User entered '3'	System	12 Apr 2021 15:39:01
User entered '2'	System	05 Apr 2021 15:20:31
User entered '1'	System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '12/Apr/2021 10:38'	(b) (4) System	12 Apr 2021 15:39:01

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 10:33:37
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 15:39:01

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'USA-US131-2021-MRNA-1273-P301000015'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:54:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:20:18
Un-reviewed for Safety.	System	05 Apr 2021 12:50:07
Signature has been broken.	System	05 Apr 2021 12:50:07
User entered 'Yes (Y)'	System	05 Apr 2021 12:50:07
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'No (N)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Yes (Y)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Paul'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'Kilgore'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) ,	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6) '	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered 'MI'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:04
User entered (b) (6)'	System	02 Apr 2021 18:53:36

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 15:20:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:33:06
User entered 'US'	(b) (4) System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:03:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Apr 2021 10:33:53
User entered '3'	System	12 Apr 2021 15:39:01
User entered '2'	System	05 Apr 2021 15:20:31
User entered '1'	System	02 Apr 2021 18:54:15

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered '13/Apr/2021 10:33'	(b) (4) System	13 Apr 2021 10:33:53

US3522128

Folder: SAE USA-US131-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:03:33

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 signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:31:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 10:33:53