

US3522109 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:01:11

All time stamps listed in this document are displayed in GMT

US3522109

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 21:23:14

Generated On: 10 Jun 2021 08:01:11

Participant ID

US3522109

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

US3522109

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3522109

Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input checked="" type="radio"/> Male <input 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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3522109

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 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 21:23:16

Generated On: 10 Jun 2021 08:01:11

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 21:23:16

Generated On: 10 Jun 2021 08:01:11

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	POST MENOPAUSE
Start date (dd MMM yyyy)	24 JAN 2013
Start date completely unknown	False
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)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	MILD ASTHMA
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)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	RIGHT KNEE ARTHRITIS
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)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	BASAL CELL CARCINOMA NOSE
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)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	BASAL CELL CARCINOMA CHEST
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)	

US3522109

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	BELL'S PALSY
Start date (dd MMM yyyy)	UN FEB 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2019
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	FEB 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	MIGRAINE HEADACHES
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)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	ENLARGED DESCENDING AORTA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	MIDDLE FINGER OF LEFT HAND JOINT SWELLING, NO KNOWN CAUSE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	MIGRATORY PAINS IN JOINTS OF KNEES, LEGS (SAW RHEMATOLOGIST, NO DIAGNOSIS)
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	KNEE REPLACEMENT SURGERY (DUE TO OSTEOARTHRITIS)
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	SEASONAL ALLERGIES
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)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	DROOPY EYELIDS INTERFERING WITH VISION
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)	

US3522109

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 09 Mar 2021 15:35:53

Generated On: 10 Jun 2021 08:01:11

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522109

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:01 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 08:01
Height (<i>xxx.x</i>)	62 in
Weight (<i>xxx.x</i>)	146.6 lb
BMI (<i>xxx.x</i>)	26.86956 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 21:23:16

Generated On: 10 Jun 2021 08:01:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*) 13 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) 24 JAN 2013

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

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 17:33:12

Generated On: 10 Jun 2021 08:01:11

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

Visit date (dd MMM yyyy)	13 AUG 2020
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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	VISIT1
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US3522109

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103703

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Height	ND - Not Done
Weight	ND - Not Done

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

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)	13 AUG 2020
Time of assessment (00:00-23:59)	08:01 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 08:01
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

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)	13 AUG 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 09:20
Temperature (xxx.x)	98.0 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 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 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 13 AUG 2020

What was the treatment time? (00:00-23:59) 08:50 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 08:50

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 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	08:10 (24 HR)
Collection date and time (derived)	13 AUG 2020 08:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:20	13 AUG 2020 08:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 09:25

PC Open Date & Time

13 AUG 2020 09:10

PC Close Date & Time

13 AUG 2020 11:40

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 13 AUG 2020 19:00

PC Open Date & Time 13 AUG 2020 12:35

PC Close Date & Time 14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 17:50

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 21:52

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

17 AUG 2020 06:15

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 04:09

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 07:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 09:36

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 09:25

PC Open Date & Time

13 AUG 2020 09:10

PC Close Date & Time

13 AUG 2020 11:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 19:02

PC Open Date & Time

13 AUG 2020 12:35

PC Close Date & Time

14 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

3

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)**

5

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 17:52

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 21:52

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 06:15

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

18 AUG 2020 04:10

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 07:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 09:36

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 09:26
PC Open Date & Time	13 AUG 2020 09:10
PC Close Date & Time	13 AUG 2020 11:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 19:03
PC Open Date & Time	13 AUG 2020 12:35
PC Close Date & Time	14 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 17:52
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:53
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 06:16
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 04:10
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 07:01
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 09:37
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3522109

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

PRESCRIPTION NAPROXEN
TAKEN ON DAY 1-2 FOR PAIN,
REDNESS AND SWELLING
SYMPTOMS, WHICH RESOLVED
BY DAY 7. RECORDED
SWELLING/HARDNESS IN CM
INSTEAD OF MM IN E-DIARY.
OTHERWISE NO OTHER
CHANGES REPORTED

US3522109

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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

US3522109

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 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

US3522109

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

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)	10 SEP 2020
Time of assessment (00:00-23:59)	07:44 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 07:44
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

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)	10 SEP 2020
Time of assessment (00:00-23:59)	09:12 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:12
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3522109

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 SEP 2020

What was the treatment time? (00:00-23:59) 08:42 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 08:42

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

US3522109

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	7:55 (24 HR)
Collection date and time (derived)	10 SEP 2020 7:55

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:58	10 SEP 2020 07:58
Nasopharyngeal Swab 2	No		

US3522109

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 09:09

PC Open Date & Time

10 SEP 2020 09:02

PC Close Date & Time

10 SEP 2020 11:32

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	10 SEP 2020 20:55
PC Open Date & Time	10 SEP 2020 12:27
PC Close Date & Time	11 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	11 SEP 2020 13:31
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

12 SEP 2020 19:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.4 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

13 SEP 2020 20:50

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 22:30

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 SEP 2020 21:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 07:24

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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

10 SEP 2020 09:05

PC Open Date & Time

10 SEP 2020 09:02

PC Close Date & Time

10 SEP 2020 11:32

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 21:02

PC Open Date & Time

10 SEP 2020 12:27

PC Close Date & Time

11 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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)**

60

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 13:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

70

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)**

95

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 19:04

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

45

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)**

70

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 20:50

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

60

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)**

55

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 22:31

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 09:06
PC Open Date & Time	10 SEP 2020 09:02
PC Close Date & Time	10 SEP 2020 11:32

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:02
PC Open Date & Time	10 SEP 2020 12:27
PC Close Date & Time	11 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 13:33
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:04
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:51
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 22:31
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

		Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 21:36	
PC Open Date & Time	15 SEP 2020 12:00	
PC Close Date & Time	16 SEP 2020 11:59	

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 8

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 18 SEP 2020 07:25

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 07:25

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

18 SEP 2020 07:25

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 SEP 2020 00:14

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 SEP 2020 19:26

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 SEP 2020 07:25

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 9

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 SEP 2020 00:14

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 8

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 SEP 2020 07:25

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:11

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	18 SEP 2020 07:25
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 9
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	19 SEP 2020 00:14
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3522109

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

ARM SWEELING AT 1ST. DAY 4
DIFFICULTY BREATHING. DAY
5 ED VISIT FOR CHEST PAIN.
D-DIMER ELEVATED (POSSIBLE
INFLAMMATORY RESPONSE).
ALL TESTS NEG. USED
ALBUTEROL ONCE. DR.
RAMESH SPOKE WITH IN ED.

US3522109

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

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

If Contact Not Made, please provide Comments

US3522109

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments PT REPORTS CHEST HEAVINESS
AND HEADACHE STARTING
30SEP2020. PT IS TAKING
ALBUTEROL INHALER AND
HAS NOT SEEN PCP. DOES NOT
BELIEVE SYMPS. RELATED TO
STUDY DRUG AND DOES NEED
TO SPEAK WITH STUDY DOC.

If Contact Not Made, please provide Comments

US3522109

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:12

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 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

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:41 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 07:41
Temperature (<i>xxx.x</i>)	98.5 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>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522109

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3522109

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	07:47 (24 HR)
Collection date and time (derived)	9 OCT 2020 07:47

US3522109

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:33:30

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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 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	16 OCT 2020 18:05:59
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 06:56:34

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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 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	27 OCT 2020 06:59:33
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 16:49:49

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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 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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	17 NOV 2020 06:40:28
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	24 NOV 2020 17:38:47
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this 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 checked="" 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 checked="" 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 checked="" type="radio"/>
Date and time of submission	28 NOV 2020 08:42:43
Patient Cloud Open Date & Time	28 NOV 2020 00:01
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US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 00:01:58

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	12 DEC 2020 14:04:41
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 01:36:02

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 00:53:54

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 13:17:18

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 00:02:04

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 00:19:53

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 20:06:53

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 01:09:52

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 00:01:41

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 00:17:49

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 00:12:44

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 11:03:37

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 14:35:34

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 02:15:05

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 00:02:26

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 00:02:53

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 00:02:42

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 00:02:44

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 01:46:27

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 01:04:02

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

Patient Cloud Open Date & Time	13 NOV 2021 00:01
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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°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="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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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

Patient Cloud Open Date & Time	15 OCT 2022 00:01
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Patient Cloud Close Date & Time	19 OCT 2022 23:59
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US3522109

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:01:11

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		02 MAR 2021 22:39:49

US3522109

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 NOV 2020

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

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."

If Contact Not Made, please provide Comments

US3522109

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

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

AES REPORTED ON 28 NOV 2020
(SOB, COUGH, FATIGUE, AND
BODY ACHES) ARE MUCH
IMPROVED BUT NOT
COMPLETELY GONE.
CONTINUES TO RECOVER
FROM RECENT ILLNESS (26
NOV 2020 TO 01 DEC 2020
HOSPITALIZATION)

US3522109

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 JAN 2021

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

Comments CALL ATTEMPTED; VM LEFT

If Contact Not Made, please provide Comments

US3522109

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

STILL TAKING PREDNISONE,
TAPERING DOWN SLOWLY,
CURRENTLY TAKING 5MG.
FOLLOWING UP WITH
RHEUMATOLOGY ON TUESDAY
TO FURTHER LOOK INTO
POSSIBLE CAUSES FOR
INFLAMMATION.

US3522109

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 15:35:54

Generated On: 10 Jun 2021 08:01:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT4

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 18:55:29

Generated On: 10 Jun 2021 08:01:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 08:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522109

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 15:35:54

Generated On: 10 Jun 2021 08:01:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3522109

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 15:35:54

Generated On: 10 Jun 2021 08:01:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	08:08 (24 HR)
Collection date and time (derived)	09 MAR 2021 08:08

US3522109

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 15:35:54

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 APR 2021

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

Comments HAS BEEN FEELING VERY
WELL AND WILL BE GOING
FOR CARDIOLOGY FOLLOW-UP
ON 13 APR 2021 WHEN SHE
HOPES TO BE TAKEN OFF THE
COLCHICINE. OTHERWISE, NO
OTHER CHANGES IN HEALTH,
NO COVID-19 EXPOSURES

If Contact Not Made, please provide Comments

US3522109

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522109

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3522109

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522109

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Date of Contact	25 NOV 2020
Time of Contact	10:30
Date and Time of Contact (derived)	25 NOV 2020 10:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3522109

Folder: Covid-19 Assessment 25 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Mar 2021 15:15:48

Generated On: 10 Jun 2021 08:01:11

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3522109

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

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

Visit date (dd MMM yyyy)	11 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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US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 15:15:48

Generated On: 10 Jun 2021 08:01:11

Date of updated informed consent (*dd MMM yyyy*) 11 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☒ Amendment 6 or later ☐

Date of unblinding (*dd MMM yyyy*) 02 DEC 2020

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	11 FEB 2021
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Collection time (00:00-23:59)	07:51 (24 HR)
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Collection date and time (derived)	11 FEB 2021 07:51
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US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00 - 23:59)	07:52
Collection Date and Time (derived)	11 FEB 2021 07:52

US3522109

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 21:23:15

Generated On: 10 Jun 2021 08:01:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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AEID	
Adverse event	PAIN IN UPPER RIGHT CHEST NOS
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)	13 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)	15 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 type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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	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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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WENT TO THE ED
COMPLAINING OF CHEST PAIN
FOR THE PAST 2 DAYS. PAIN
EXACERBATED WITH LEANING
FORWARD AND DEEP
INSPIRATION. TOOK ASPIRIN,
NAPROXEN LAST NIGHT.
CHEST PAIN, UNSPECIFIED
TYPE:
DIAGNOSIS MANAGEMENT
COMMENTS: PT PRESENTS
WITH SOME DIZZINESS AND
RIGHT SIDED CHEST PAIN. PT
DID RECEIVE SECOND DOSE OF
THE COVID VACCINE 5 DAYS
AGO. BENIGN EXAM AND
NORMAL VITALS. LAB WORK IS
SIGNIFICANT FOR ELEVATED
D-DIMER. CT CHEST IS
NEGATIVE FOR PE OR ANY
OTHER ACUTE PROCESS. PT
WILL BE DISCHARGED TO
FOLLOW UP WITH PCP.
PATIENT UNDERSTANDS AND
AGREES WITH TREATMENT
PLAN.

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 (2)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	
Adverse event	CHEST HEAVINESS INTERMITTENT
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	30 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)	03 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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	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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

DESCRIBED TO STAFF AS
CHEST HEAVINESS, ALSO AS
UPPER RIGHT CHEST PAIN
RETURNED AFTER HAVING
BEEN GONE AFTER HOSPITAL
VISIT ON 15SEP2020. STARTED
AGAIN INTERMITTANTLY ON
30SEP2020 AND WAS UNTIL
03OCT2020. DURING PCP VISIT
ON 05OCT2020 HAD NO ISSUES.
WAS ASYMPTOMATIC AT VISIT
3 ON 09 OCT 2020. USED
ALBUTEROL INHALER TO TRY
TO HELP AND NAPROXEN THAT
ALSO IS TAKEN FOR ASTHMA
AND KNEE PAIN
RESPECTIVELY. PAIN
APPEARED TO GO AWAY OVER
TIME

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)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	30 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)	03 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (3)

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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 ☒
Related ☐
Not Applicable ☐

Relationship to Study Procedure Not Related ☒
Related ☐
Not Applicable ☐

Action taken with investigational product None ☒
Dose Delayed ☐
Investigational Product ☐
Withdrawn ☐
Not Applicable ☐

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐
Not Recovered/Not Resolved ☐
Recovered/Resolved ☒
Recovered/Resolved with Sequelae ☐
Recovering/Resolving ☐
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative ALONG WITH THE CHEST HEAVINESS (SEE AE LOG LINE 2) HAD A HEADACHE. THIS ALSO WAS NOT PRESENT AT THE TIME OF THE VISIT TO THE PCP ON 05 OCT 2020, HOWEVER IT WAS STILL PRESENT ON THE DAY 50 SAFETY CALL ON 01 OCT 2020.

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Folder: Adverse Events

Form: Adverse Events (3)

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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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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AEID

Adverse event

UPPER ABDOMEN/CHEST
DISCOMFORT (RELATED TO
PERICARDIAL EFFUSION)

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)

15 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 FEB 2021

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 ☐

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Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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	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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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PASSED OUT 15 NOV 2020
AFTER FEELING NAUSEOUS
AND GOING ON KNEES. HR
VARIED 81-117, DISCOMFORT IN
UPPER ABDOMEN SIMILAR TO
RIGHT-SIDED CHEST PAIN
FROM PREVIOUS. PRESSURE
WHEN BENDING OVER AND A
FLEETING FLUTTERING
SENSATION IN
ABDOMEN. WENT TO PCP 16
NOV2020, PULSE AT VISIT 114
BPM. ORDERED LABS
(CBC/METAB PROFILE,
THYROID SCREEN), ECG 12
LEAD. ORDERED CT. .CT SCAN
CAME BACK WITH NEW
MODERATE PERICARDIAL
EFFUSION WITH DIFFUSE
PERICARDIAL ENHANCEMENT.
AND NEW SMALL BILATERAL
PLEURAL EFFUSIONS LEFT
GREATER THAN RIGHT. HAD
CARDIOLOGY CONSULT
18NOV2020. STARTED ON
COLCHICINE AND HIGH
INTENSITY ASPIRIN BASED ON
PREVIOUS CT SCAN RESULT.
ORDERED AN
ECHOCARDIOGRAM, BNP,
TROPONIN I, ANA SCREEN AND
TITER, ERYTHROCYTE
SEDIMENTATION RATE. LATER
WENT TO HOSPITAL 26
NOV2020 DUE TO PAIN,

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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DISCHARGED ON 01 DEC 2020.
UNBLINDED FROM STUDY.
WENT TO PCP ON 04 DEC 2020
AND DID NOT REPORT PAIN
THEN. SPOKE WITH PATIENT
AGAIN 14-JAN-2021 WHO
STATES THAT SHE STILL HAS
OCCASIONAL
CHEST/ABDOMINAL PAIN THAT
IS LIKELY RELATED TO THE
FLUID AROUND HER HEART. IT
IS SIGNIFICANTLY BETTER
THAN BEFORE, AND SHE IS IN
THE PROCESSING OF COMING
OFF OF PREDNISONE.

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 (5)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	USA-US131-2020-MRNA-1273-P30 1000011
Adverse event	PERICARDIAL EFFUSION
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)	16 NOV 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)	22 FEB 2021
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)	26 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	01 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Form: Adverse Events (5)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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Number of Days in ICU	
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 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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

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Form: Adverse Events (5)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

15NOV2020 PARTICIPANT
PASSED OUT AFTER KNEELING
ON FLOOR AFTER NAUSEAU
SPELL. FELT CHEST
HEAVINESS/PAIN AS
PREVIOUSLY REPORTED.
PRESSURE WHEN LEANING
FORWARD. HR OBSERVED
BETWEEN 84-117. 16NOV2020
WENT TO PCP. HR 114.
ORDERED CBC, COMP.
METABOLISM, THYROID, AND
12 LEAD EKG. CT SCAN
ORDERED, PERFORMED ON
17NOV2020. INITIALLY
THOUGHT TO BE POSSIBLY
RELATED TO HISTORY OF
AORTIC ECTASIA, THORACIC.
HIGH INTENSITY ASPIRIN WAS
RECOMMENDED. CT SCAN
SHOWED MODERATE
PERICARDIAL EFFUSION AND
SMALL BILATERAL PLEURAL
EFFUSIONS. ORDERED
ECHOCARDIOGRAM, REVEALS
CIRCUMFERENTIAL
PERICARDIAL EFFUSION.
ETIOLOGY DETERMINED
REACTIVE (VIRAL OR
INFLAMMATORY). COLCHICINE
IS ADDED TWICE A DAY. BNP,
TROPONIN, ANA, AND ESR
LABS REQUESTED. PAIN
CONTINUED IN CHEST ALONG
WITH RISING FATIGUE AND

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

EPIGASTRIC PAIN, WENT TO ER
ON 26 NOV 2020. LABS
ORDERED CBC AND DIFF..
BASIC METAB, BNP, TROPONIN
1, MAGNESIUM, ESR,
PROCALCITONIN. CT CHEST
WITH IV CONTRAST
PULMONARY EMBOLISM
DONE, WAS NEGATIVE FOR PE.
PERICARDIAL EFFUSION WAS
MILD TO MODERATE. 27 NOV
2020, ECHOCARDIOGRAM
ORDERED, PERICARDIAL
EFFUSION SEEN AS TRIVIAL.
MEDICATIONS CHANGED IS
HIGH INTENSITY ASPIRIN
DISCONTINUED AND
COLCHICINE FOR 3 MONTHS
AND PREDNISONE TAPER.
PATIENT SAW CARDIOLOGIST
13-JAN-2021 WHO
RECOMMENDED CONTINUING
TO TAPER PREDISONE AND
NOTED NO PERICARDIAL RUB
ON EXAM THOUGH SHE DOES
STILL HAVE OCCASIONAL
CHEST/UPPER ABOMINAL PAIN
THAT IS LIKELY RELATED TO
THE PERICARDIAL FLUID. SHE
WILL FOLLOW UP WITH
CARDIOLOGY AGAIN IN APRIL
2021.

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: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	USA-US131-2020-MRNA-1273-P30 1000011
Adverse event	PERICARDITIS
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)	16 NOV 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)	22 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input 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)	26 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	01 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Form: Adverse Events (6)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

Number of Days in ICU	
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 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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

PT STATES SHE SAW PCP ON MONDAY 16 NOV FOR CHEST PAIN SHE WAS EXPERIENCING. REFERRED TO CARDIOLOGIST FOR TESTING THAT WAS DONE ON 18 NOV AND DIAGNOSED WITH PERICARDITIS AND PERICARDIAL EFFUSION. WENT TO THE ER FOR CHEST PAIN ON 26NOV2020 AND WAS DISCHARGE ON 01DEC2020. STUDY TEAM REQUESTING TO UNBLIND. MORE DETAILED INFORMATION ON TESTS IN PERICARDIAL EFFUSION LOG LINE. APPEARS TO HAVE BEEN RESPONSIBLE FOR EPISODIC ATRIAL FLUTTER. PATIENT SAW CARDIOLOGIST 16-DEC-2020 AND AGAIN 13-JAN-2021. CARDIOLOGY NOTES THAT SHE IS SYMPTOMATICALLY MUCH BETTER WITH THE PREDNISONE, ONLY OCCASIONAL CHEST/UPPER ABDOMEN PAIN, NO PERICARDIAL RUB, WILL CONTINUE WITH A SLOW PREDNISONE TAPER AND DISCONTINUE. WILL FOLLOW UP AGAIN WITH RHEUMATOLOGY IN LATER JAN 2021 AND CARDIOLOGY IN APRIL 2021.

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: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	
Adverse event	GASTRO-ESOPHAGEAL REFLUX DISEASE
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)	01 DEC 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)	22 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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 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	

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

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OBSERVED DURING
HOSPITALIZATION VISIT, WAS
MENTIONED ONLY ON
DISCHARGE ON 01DEC2020.
WAS GIVEN FOR WHILE ON
PREDNISONE ONLY. ENDED
WHEN PREDNISONE WAS
DISCONTINUED ON 22 FEB 2021

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)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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AEID	
Adverse event	FATIGUE
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)	15 NOV 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)	2 DEC 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

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Data signed: (b) (4) 19 Apr 2021 19:00:12

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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 ☐

Related ☒

Not Applicable ☐

Relationship to Study Procedure Not Related ☒

Related ☐

Not Applicable ☐

Action taken with investigational product None ☐

Dose Delayed ☐

Investigational Product ☐

Withdrawn ☐

Not Applicable ☒

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐

Not Recovered/Not Resolved ☐

Recovered/Resolved ☒

Recovered/Resolved with ☐

Sequelae

Recovering/Resolving ☐

Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

FOLLOWS THE NARRATIVE
FOR ABDOMINAL
DISCOMFORT/CHEST PAIN ON
15 NOV 2020. FELT FATIGUED
AND CONTINUES TO REPORT
VARIOUS LEVELS OF FATIGUE
UNTIL 04 DEC 2020. COVID
SWAB TEST DONE ON 25 NOV
2020 AND WAS NEGATIVE.

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Folder: Adverse Events

Form: Adverse Events (8)

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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 (9)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	15 NOV 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)	15 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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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 ☒
Related ☐
Not Applicable ☐

Relationship to Study Procedure Not Related ☒
Related ☐
Not Applicable ☐

Action taken with investigational product None ☐
Dose Delayed ☐
Investigational Product ☐
Withdrawn ☐
Not Applicable ☒

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐
Not Recovered/Not Resolved ☐
Recovered/Resolved ☒
Recovered/Resolved with Sequelae ☐
Recovering/Resolving ☐
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative BOUT OF NAUSEA REPORTED TO PCP ON 16 NOV 2020 AS STARTED ON 15 NOV 2020. APPEARS TO HAVE GONE AWAY.

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)

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	USA-US131-2020-MRNA-1273-P30 1000011
Adverse event	EPISODIC ATRIAL FLUTTER
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)	26 NOV 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)	01 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	26 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	01 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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 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	

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

EPISODIC ATRIAL FLUTTER
OBSERVED DURING
TELEMETRY DURING
HOSPITAL VISIT. NOT SEEN AS
A CONCERN, VIEWED AS
RELATED TO THE
PERICARDITIS (SEE OTHER AE).
WAS GIVEN METOPROLOL
TARTRATE 25 MG. NOT
OBSERVED DURING PCP CHECK
UP AFTER HOSPITALIZATION
ON 04 DEC 2020. ALSO NOT
OBSERVED OR REPORTED ON
VISIT TO CARDIOLOGIST
13-JAN-2021. HAS NOT HAD
ANY SYMPTOMS SINCE
HOSPITALIZATION. IS STILL
TAKING METOPROLOL AS A
PRECAUTION BUT LIKELY
THAT IS NOT LONG TERM.
CARDIOLOGIST BELIEVES
IRRITATION FROM THE
PERICARDITIS WAS WHAT
CAUSED THE AFIB, AND THAT
IT HAS RESOLVED NOW.

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: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	USA-US131-2020-MRNA-1273-P30 1000011
Adverse event	PLEURAL EFFUSIONS (BILATERAL)
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)	17 NOV 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)	22 FEB 2021
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)	26 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	01 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
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	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

NEW SMALL PLEURAL
EFFUSIONS (BILATERAL, LEFT
GREATER THAN RIGHT)
OBSERVED IN CT SCAN
PERFORMED ON 17 NOV 2020.
AFTER GOING TO HOSPITAL ON
26NOV2020 (SEE PERICARDIAL
EFFUSION NARRATIVE), CT
FOUND THAT THERE WAS A
MILD TO MODERATE LEFT AND
SMALL RIGHT PLEURAL
EFFUSION. THORACENTESIS
PERFORMED ON 30 NOV2020 ON
THE MODERATE LEFT
PLEURAL EFFUSION
REMOVING 450 CC OF CLEAR
YELLOW FLUID WHICH WAS
ANALYZED AND FOUND
NEGATIVE FOR
BACTERIA/FUNGI. NO NEW
IMAGING ON FILE AFTER
30NOV2020. PARTICIPANT
DEEMED STABLE AND
RELEASED FROM HOSPITAL. AS
OF 04DEC2020 IS NOT
REPORTING SHORTNESS OR
BREATH OR PLEURODYNIA.
APPOINTMENT WITH
CARDIOLOGY ON 16DEC2020
AND 13 JAN 2021. NOTED ON
PERICARDIAL RUB ON EXAM
BUT NO REPEAT IMAGING WAS
ORDERED. 22-FEB-2021
WEANED OFF OF PREDNISONE,
ASYMPTOMATIC WITH NO
SHORTNESS OF BREATH OR
CHEST PAIN. NO
PULMONOLOGY FOLLOW UP
APPOINTMENT SCHEDULE AT
THIS TIME.

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: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	
Adverse event	MELANOMA IN SITU (LEFT SHOULDER)
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)	22 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)	5 NOV 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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	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	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

SHE HAD A SKIN CHECK WITH
DERMATOLOGY IN 22 OCT 2020
AND TWO LESIONS WERE
DISCOVERED. A LESION ON
LEFT SHOULDER WAS
BIOPSIED ON 05 NOV 2020 AND
WAS MELANOMA IN SITU WITH
CLEAR MARGINS AND DID NOT
REQUIRE TREATMENT; A
SECOND ON THE LEFT CHEEK
WAS ACTINIC KERATOSIS AND
SHE RECEIVED RED-LIGHT
TREATMENT FOR IT ON 13 NOV
2020.

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 (13)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	
Adverse event	ACTINIC KERATOSIS (LEFT CHEEK)
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)	22 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)	13 NOV 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 19 Apr 2021 19:00:12

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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	False
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	

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

SHE HAD A SKIN CHECK WITH
DERMATOLOGY IN 22 OCT 2020
AND TWO LESIONS WERE
DISCOVERED. A LESION ON
LEFT SHOULDER WAS
BIOPSIED ON 05 NOV 2020 AND
WAS MELANOMA IN SITU WITH
CLEAR MARGINS AND DID NOT
REQUIRE TREATMENT; A
SECOND ON THE LEFT CHEEK
WAS ACTINIC KERATOSIS AND
SHE RECEIVED RED-LIGHT
TREATMENT (PHOTODYNAMIC
THERAPY) FOR IT ON 13 NOV
2020.

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 (14)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	13 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)	18 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (14)

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Generated On: 10 Jun 2021 08:01:11

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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 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	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:	
<hr/>	
Narrative	
<hr/>	
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)	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

AEID	
Adverse event	MYALGIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	17 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)	17 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 19 Apr 2021 19:00:12

Generated On: 10 Jun 2021 08:01:11

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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 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	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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 21:23:15

Generated On: 10 Jun 2021 08:01:11

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication KNEE PAIN

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

TWICE DAILY WITH FOOD AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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) _____		
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication FLUBLOK RIV4

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	Intramuscular	<input checked="" 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)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication ALBUTEROL (PROVENTIL)
NEBULIZER SOLUTION

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2.5/3/0.083

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MG/ML/%

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 (3)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)		
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication SINUS CONGESTION

Dose per administration 50

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) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication ASPIRIN EC

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 650

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration 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) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	25 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication ASPIRIN EC

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS/ PERICARDIAL
EFFUSION

Dose per administration 650

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	25 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 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) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 0.6

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 NOV 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"/>

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 DEC 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 (9)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PROTONIX

Prophylaxis Yes ☒
No ☐

Indication GASTRO ESOPHAGEAL REFLUX
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	29 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication DIPHENHYDRAMINE-ZINC
ACETATE

Prophylaxis Yes ☐
No ☒

Indication ITCHING SECONDARY TO
SEASONAL ALLERGIES

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify TOPICAL APPLICATION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		01 DEC 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐
No ☒

Indication EPISODIC ATRIAL FLUTTER

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 (11)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 DEC 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"/>

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication MAALOX PLUS (ALUMINUM
AND MAGNESIUM
HYDROXIDE-SIMETHICONE)

Prophylaxis Yes ☐
No ☒

Indication GASTRO ESOPHAGEAL REFLUX
DISEASE

Dose per administration 30

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	Transdermal	<input type="checkbox"/>
	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)	26 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 NOV 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 (13)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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 (13)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 DEC 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) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication LIDOCAINE HCL 2% VISCOUS SOLUTION

Prophylaxis Yes ☐
No ☒

Indication GASTRO ESOPHAGEAL REFLUX DISEASE

Dose per administration 15

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		26 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 NOV 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 (15)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication ROBAXIN

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
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) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication VENOUS THROMBOEMBOLISM
PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 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 (17)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 650

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

AS NEEDED EVERY 6 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) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 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) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF ISSUES
DURING HOSPITALIZATION:
ELECTROLYTE REPLACEMENT

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 TWICE

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		28 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 NOV 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 (19)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication POTASSIUM BICARB-CITRIC
ACID

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF ISSUES
DURING HOSPITALIZATION:
ELECTROLYTE REPLACEMENT

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 TWICE

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	Transdermal	<input type="checkbox"/>
	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 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 (20)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION

Dose per administration 17

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 NOV 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 (21)

Data signed: (b) (4) 12 Apr 2021 11:53:34

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Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 15

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 (21)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		30 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 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 (22)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication LACTULOSE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		02 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 35

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 (24)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		08 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 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 (25)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 30

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 (25)

Data signed: (b) (4) 12 Apr 2021 11:53:34

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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)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 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 (26)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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 (26)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	03 JAN 2021	
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 (27)

Data signed: (b) (4) 12 Apr 2021 11:53:34

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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 (27)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		30 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 12 Apr 2021 11:53:34

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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 (28)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 15

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 (30)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	05 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 15

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 (31)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	15 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 JAN 2021
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 (32)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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 (32)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 12.5

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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 (34)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 JAN 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"/>

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 7.5

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 FEB 2021
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 (37)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 2.5

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication PERICARDITIS

Dose per administration 2.5

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication BOTOX-A INJECTION

Prophylaxis Yes ☐
No ☒

Indication FACIAL RHYTIDES (GLABELLA
AND CROWS FEET)

Dose per administration 28

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 (40)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 MAR 2021
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 (41)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

Name of Medication RESTYLANE DERMAL FILLER

Prophylaxis Yes ☐
No ☒

Indication COSMETIC (FACE)

Dose per administration 1

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 (41)

Data signed: (b) (4) 12 Apr 2021 11:53:34

Generated On: 10 Jun 2021 08:01:11

	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)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 MAR 2021
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 21:23:16

Generated On: 10 Jun 2021 08:01:11

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Mar 2021 15:15:48

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 SEP 2020	CT CHEST WITH IV CONTRAST PULMONARY EMBOLISM	Diagnostic	
15 SEP 2020	CBC AND DIFFERENTIAL	Diagnostic	
15 SEP 2020	BASIC METABOLIC PROFILE	Diagnostic	
15 SEP 2020	TROPONIN I	Diagnostic	
15 SEP 2020	PT/INR/PTT	Diagnostic	
15 SEP 2020	D-DIMER, QUANTITATIVE	Diagnostic	
17 NOV 2020	CT ANGIOGRAPHY CHEST GATED WITH IV CONTRAST (**NON-CORONARY**)	Diagnostic	
16 NOV 2020	ECG 12 LEAD	Diagnostic	
18 NOV 2020	BNP	Diagnostic	
18 NOV 2020	TROPONIN I	Diagnostic	
18 NOV 2020	ANA SCREEN AND TITER	Diagnostic	
18 NOV 2020	ERYTHROCYTE SEDIMENTATION RATE	Diagnostic	
25 NOV 2020	2019 NCORONAVIRUS, PCR (COVID-19)	Diagnostic	
26 NOV 2020	CBC AND DIFFERENTIAL	Diagnostic	
26 NOV 2020	BASIC METABOLIC PROFILE	Diagnostic	
26 NOV 2020	BNP	Diagnostic	
26 NOV 2020	TROPONIN I	Diagnostic	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Data signed: (b) (4) 12 Mar 2021 15:15:48

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 NOV 2020	MAGNESIUM	Diagnostic	
26 NOV 2020	ERYTHROCYTE SEDIMENTATION RATE	Diagnostic	
26 NOV 2020	PROCALCITONIN	Diagnostic	
27 NOV 2020	TROPONIN I	Diagnostic	
27 NOV 2020	BASIC METABOLIC PROFILE	Diagnostic	
27 NOV 2020	C-REACTIVE PROTEIN	Diagnostic	
27 NOV 2020	CBC	Diagnostic	
27 NOV 2020	MAGNESIUM	Diagnostic	
27 NOV 2020	PHOSPHORUS	Diagnostic	
27 NOV 2020	ANA SCREEN AND TITER	Diagnostic	
27 NOV 2020	HIV 4TH GENERATION ANTIGEN/ANTIBODY COMBO	Diagnostic	
27 NOV 2020	BLOOD CULTURE	Diagnostic	
27 NOV 2020	HISTOPLASMA AG, QUANT	Diagnostic	
28 NOV 2020	BASIC METABOLIC PROFILE	Diagnostic	
28 NOV 2020	CBC AND DIFFERENTIAL	Diagnostic	
28 NOV 2020	LIVER PROFILE	Diagnostic	
28 NOV 2020	MAGNESIUM	Diagnostic	
28 NOV 2020	T4, FREE	Diagnostic	

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Data signed: (b) (4) 12 Mar 2021 15:15:48

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 NOV 2020	TSH	Diagnostic	
28 NOV 2020	PHOSPHORUS	Diagnostic	
28 NOV 2020	RESPIRATORY VIRUS PANEL PCR	Diagnostic	
28 NOV 2020	FLU A/B AND RSV PCR, NASOPHARYNX	Diagnostic	
28 NOV 2020	PT/INR/PTT	Diagnostic	
29 NOV 2020	BASIC METABOLIC PROFILE	Diagnostic	
29 NOV 2020	CBC AND DIFFERENTIAL	Diagnostic	
29 NOV 2020	MAGNESIUM	Diagnostic	
29 NOV 2020	PHOSPHORUS	Diagnostic	
30 NOV 2020	BASIC METABOLIC PROFILE	Diagnostic	
30 NOV 2020	CBC AND DIFFERENTIAL	Diagnostic	
30 NOV 2020	MAGNESIUM	Diagnostic	
30 NOV 2020	PHOSPHORUS	Diagnostic	
30 NOV 2020	CELL COUNT AND DIFFERENTIAL, PLEURAL FLUID	Diagnostic	
30 NOV 2020	FLUID CULTURE, NON-CSF (ANAEROBIC/AEROBIC) WITH GRAM STAIN	Diagnostic	
30 NOV 2020	PROTEIN, PLEURAL FLUID	Diagnostic	
30 NOV 2020	LDH, PLEURAL FLUID	Diagnostic	

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (54)

Data signed: (b) (4) 12 Mar 2021 15:15:48

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 NOV 2020	FUNGAL CULTURE, PLEURAL FLUID	Diagnostic	
30 NOV 2020	AFB CULTURE, PLEURAL FLUID	Diagnostic	
30 NOV 2020	GLUCOSE, PLEURAL FLUID	Diagnostic	
30 NOV 2020	PH, PLEURAL FLUID	Diagnostic	
30 NOV 2020	ADENOSINE DEAMINASE, PLEURAL FLUID	Diagnostic	
01 DEC 2020	COVID-19 ANTIBODY, IGG	Diagnostic	
01 DEC 2020	BASIC METABOLIC PROFILE	Diagnostic	
01 DEC 2020	MAGNESIUM	Diagnostic	
01 DEC 2020	PHOSPHORUS	Diagnostic	
01 DEC 2020	LDH, TOTAL	Diagnostic	
04 DEC 2020	CBC AND DIFFERENTIAL	Diagnostic	
04 DEC 2020	C-REACTIVE PROTEIN	Diagnostic	
04 DEC 2020	ERYTHROCYTE SEDIMENTATION RATE	Diagnostic	
26 NOV 2020	ECG 12 LEAD 1 OF 2	Diagnostic	
26 NOV 2020	ECG	Diagnostic	
26 NOV 2020	ECG 12 LEAD 2 OF 2	Diagnostic	
27 NOV 2020	TELEMETRY MONITORING (UNTIL 01DEC2020)	Diagnostic	

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (71)

Data signed: (b) (4) 12 Mar 2021 15:15:48

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 NOV 2020	ECG 12 LEAD	Diagnostic	
28 NOV 2020	ECG 12 LEAD	Diagnostic	
26 NOV 2020	CXR-PAL	Diagnostic	
26 NOV 2020	CT CHEST WITH IV CONTRAST PULMONARY EMBOLISM	Diagnostic	
27 NOV 2020	ECHOCARDIOGRAM	Diagnostic	
29 NOV 2020	CHEST MARKING (FOR THORACENTESIS)	Adverse Event	
30 NOV 2020	THORACENTESIS	Adverse Event	
30 NOV 2020	CHEST 1 VIEW (INCLUDING PORTABLE)	Adverse Event	
30 NOV 2020	CYTOLOGY PLEURAL FLUID	Diagnostic	
13 NOV 2020	PHOTODYNAMIC THERAPY (RED LIGHT)	Adverse Event	
5 NOV 2020	EXCISION BIOPSY OF LEFT SHOULDER AND LEFT CHEEK SKIN LESIONS	Diagnostic	
17 FEB 2021	BLEPHAROPLASTY	Medical History	
02 MAR 2021	DIAGNOSTIC ULTRASOUND BILATERAL HANDS	Diagnostic	

US3522109

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:01:11

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3522109

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:01:11

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	30/NOV/2020 11:35
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	03/DEC/2020 11:27
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	06/DEC/2020 09:06
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	08/DEC/2020 10:09
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	08/DEC/2020 15:47
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	15/JAN/2021 08:26
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (7)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	03/FEB/2021 11:10
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (8)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	01/MAR/2021 09:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (9)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	08/MAR/2021 14:59
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (10)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	10/MAR/2021 09:57
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

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (11)

Data signed: (b) (4) 12 Apr 2021 11:53:35

Generated On: 10 Jun 2021 08:01:11

SAEID	USA-US131-2020-MRNA-1273-P301000011
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)	11
Date of submission (Pre-filled from custom function)	07/APR/2021 06:13
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

US3522109 (Prod: Henry Ford Health System)

US3522109

Form: Participant Creation

Generated On: 10 Jun 2021 08:01:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'US3522109'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 11:59:17

US3522109

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:05:43

US3522109

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 11:59:18

US3522109

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[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 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:05:43

US3522109

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'SCRN'	System	13 Aug 2020 12:05:43

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '(b) (6)' 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 11:59:19

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '59'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'YEARS'	System	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '59'	System	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:01:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:07:57

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Aug 2020'	System	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2020'	System	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:08:08

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 11:59:18

US3522109

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:01:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'I'	System	13 Aug 2020 12:08:19

US3522109

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:01:11

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:08:19

US3522109

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:01:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	08 Sep 2020 12:13:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 12:08:29

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:14:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:14:53
Data point term sent to Coder	System	08 Sep 2020 12:13:59
User entered 'Post Menopause'	Sharon Mathys (b) (4)	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '24 Jan 2013' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	03 Oct 2020 15:08:40
User entered empty.	(b) (4)	
	Sharon Mathys (b) (4)	08 Sep 2020 12:13:59
	(b) (4)	

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0' reason for change: Data Entry Error	(b) (4) Sharon Mathys (b) (4)	03 Oct 2020 15:08:40
User entered '1'	(b) (4) Sharon Mathys (b) (4)	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2013'	System	03 Oct 2020 15:08:40
User entered empty.	System	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2013'	System	03 Oct 2020 15:08:40
User entered empty.	System	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	08 Sep 2020 12:13:59

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
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)	05 Oct 2020 07:44:24
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 'added albuterol. participant did not inform because they had not used in some time.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:08:08
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 05:06:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:06:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 14:06:49
Data point term sent to Coder	System	09 Sep 2020 14:05:58
User entered 'Mild Asthma'	Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	Sharon Mathys (b) (4)	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	Sharon Mathys (b) (4)	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Sep 2020 14:05:14

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of KNEE PAIN. 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) (4), (b) (6)	26 Oct 2020 04:31:11
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:36:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:36:44
Data point term sent to Coder	System	22 Oct 2020 15:35:42
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of KNEE PAIN. 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)	22 Oct 2020 15:35:13
' answered with 'updated' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 15:35:07
User entered 'Right Knee arthritis' reason for change: New Information	(b) (4), (b) (6)	22 Oct 2020 15:35:07
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of KNEE PAIN. 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)	21 Oct 2020 08:53:17
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:06:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:06:46

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	09 Sep 2020 14:05:59
User entered 'Knee Pain'	Sharon Mathys (b) (4)	09 Sep 2020 14:05:24
	(b) (4)	

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	Sharon Mathys (b) (4)	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Sep 2020 14:05:24

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma face - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:37:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:37:54
Data point term sent to Coder	System	17 Dec 2020 16:37:23
User entered 'Basal Cell Carcinoma Nose'	Sharon Mathys (b) (4)	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	Sharon Mathys (b) (4)	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:36:36

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:48:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:48:53
Data point term sent to Coder	System	17 Dec 2020 16:37:23
User entered 'Basal Cell Carcinoma Chest'	Sharon Mathys (b) (4)	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:37:02

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Facial cranial nerve disorders, PT: Facial paralysis, LLT: Bell's palsy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:39:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:39:42
Data point term sent to Coder	System	17 Dec 2020 16:38:24
User entered 'Bell's Palsy'	Sharon Mathys (b) (4)	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un Feb 2019'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un Feb 2019'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Feb 2019'	System	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2019'	System	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Feb 2019'	System	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2019'	System	17 Dec 2020 16:37:55

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:39:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:39:42
Data point term sent to Coder	System	17 Dec 2020 16:38:24
User entered 'Migraine Headaches'	Sharon Mathys (b) (4)	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	17 Dec 2020 16:38:11

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Aneurysm of descending aorta - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:47:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:47:51
Data point term sent to Coder	System	17 Dec 2020 16:39:25
User entered 'Enlarged Descending Aorta'	Sharon Mathys (b) (4)	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un UNK 2017'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un UNK 2017'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2017'	System	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2017'	System	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2017'	System	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2017'	System	17 Dec 2020 16:38:44

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Joint swelling, LLT: Joint swelling of hand - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:47:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:47:50
Data point term sent to Coder	System	17 Dec 2020 16:40:25
User entered 'Middle Finger of Left Hand Joint Swelling, no known cause'	Sharon Mathys (b) (4)	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un UNK 2019'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un UNK 2019'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2019'	System	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2019'	System	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2019'	System	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2019'	System	17 Dec 2020 16:39:35

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in joint involving lower leg - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:50:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:50:13
Data point term sent to Coder	System	17 Dec 2020 16:41:26
User entered 'Migratory Pains in joints of knees, legs (Saw rheumatologist, no diagnosis)'	Sharon Mathys (b) (4)	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un UNK 2013'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un UNK 2013'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2013'	System	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2013'	System	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2013'	System	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2013'	System	17 Dec 2020 16:40:29

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:56:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:56:12
Data point term sent to Coder	System	17 Dec 2020 16:43:28
User entered 'KNEE REPLACEMENT Surgery (due to Osteoarthritis)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Dec 2020 16:43:02
Data point term sent to Coder	System	17 Dec 2020 16:42:28
User entered 'Knee replacement'	Sharon Mathys (b) (4)	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un UNK 2013'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'un UNK 2013'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Sharon Mathys (b) (4) (b) (4)	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2013'	System	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2013'	System	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'Jan 2013'	System	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '2013'	System	17 Dec 2020 16:41:46

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 15:27:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 15:27:46
Data point term sent to Coder	System	18 Dec 2020 15:26:18
User entered 'seasonal allergies'	Alayna Wilder (b) (4)	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Alayna Wilder (b) (4)	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) Alayna Wilder (b) (4)	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Alayna Wilder (b) (4)	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) Alayna Wilder (b) (4) (b) (4)	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	18 Dec 2020 15:26:00

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User coded data point as SOC: Eye disorders, HLGT: Ocular neuromuscular disorders, HLT: Eyelid movement disorders, PT: Eyelid ptosis, LLT: Eyelid ptosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 10:36:45
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 10:36:45
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	09 Mar 2021 15:35:54
Data point term sent to Coder	System	09 Mar 2021 13:30:05
User entered 'Droopy eyelids interfering with vision'	(b) (4), (b) (6)	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	09 Mar 2021 13:30:04

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:01:11

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '08:01'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '13 Aug 2020 08:01'	System	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '62' in	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:10:06
DataPoint set to visible.	System	13 Aug 2020 12:08:19

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '146.6' lb	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:10:06
DataPoint set to visible.	System	13 Aug 2020 12:08:19

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
Amendment Manager: User entered '26.86956'	System	16 Sep 2020 23:54:41
User entered '26.9'	System	13 Aug 2020 12:10:06
DataPoint set to visible.	System	13 Aug 2020 12:08:19

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'kg/m2'	System	13 Aug 2020 12:10:06
DataPoint set to visible.	System	13 Aug 2020 12:08:19

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:09:30
User entered '97.9' F	(b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
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 14:52:48
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 12:22:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 12:22:03
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 05:59:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	17 Aug 2020 13:09:30
User entered 'Other (Other)'	(b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 13:09:30
User entered 'temporal'	(b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:09:30
User entered '64'	(b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'bpm'	System	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:09:30
User entered '16'	(b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'breaths/min'	System	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:09:30
User entered '132'	(b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'mmHg'	System	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:09:30
User entered '85'	(b) (4), (b) (6)	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'mmHg'	System	13 Aug 2020 12:10:06

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32

US3522109

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:10:13

US3522109

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
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 17:47:42
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 11:41:02
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 12:10:13

US3522109

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:11:09

US3522109

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:11

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:11:09

US3522109

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:11

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 07:57:50
Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'added' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	08 Sep 2020 12:14:05
User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 10:45:27
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	13 Aug 2020 12:11:09

US3522109

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:11

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:11:09

US3522109

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:11

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:11:09

US3522109

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:11

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:11:09

US3522109

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:11

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '24 Jan 2013' reason for change: New Information	Sharon Mathys (b) (4)	03 Oct 2020 15:14:56
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	13 Aug 2020 12:11:37
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	13 Aug 2020 12:11:09
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 12:11:09

US3522109

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:01:11

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0' reason for change: New Information	(b) (4) Sharon Mathys (b) (4)	03 Oct 2020 15:14:56
User entered '1' reason for change: New Information	(b) (4), (b) (6)	13 Aug 2020 12:11:37
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 12:11:09

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

[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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

[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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

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)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:01:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:24

US3522109

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:36

US3522109

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:36

US3522109

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[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 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:36

US3522109

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'VISIT1'	System	13 Aug 2020 12:12:36

US3522109

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:11

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 11:59:27

US3522109

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:11

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:04:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:04:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 11:59:27
User entered '103703' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 11:59:27

US3522109

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	13 Aug 2020 11:59:27

US3522109

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:11

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 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:54

US3522109

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:11

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 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:54

US3522109

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:11

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:54

US3522109

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:11

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:54

US3522109

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:01:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:12:54

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:10:26
User entered '62' in	(b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	17 Aug 2020 13:10:26
User entered '146.6' lb	(b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:10:26
User entered '62' in	(b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:10:26
User entered '146.6' lb	(b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '08:01'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '13 Aug 2020 08:01'	System	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User closed query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." (Site from System).	(b) (4)	17 Sep 2020 13:22:08
Query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." answered by data change (Site from System).	System	17 Sep 2020 13:22:08
User entered '36.6' C reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Sep 2020 13:22:08
Amendment Manager: User opened query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." (Site from System).	(b) (4)	16 Sep 2020 23:54:41
User entered '36.6' F	System	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '64'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'bpm'	System	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'breaths/min'	System	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '132'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '85'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:10:26
User entered '62' in	(b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:01:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	17 Aug 2020 13:10:26
User entered '146.6' lb	(b) (4), (b) (6)	13 Aug 2020 13:21:49

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
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 15:31:35
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).		13 Aug 2020 13:22:31
User entered '09:20'	(b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '13 Aug 2020 09:20'	System	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '78'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'bpm'	System	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '18'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'breaths/min'	System	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '133'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '95'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	13 Aug 2020 13:22:31

US3522109

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Aug 2020 16:12:21
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	13 Aug 2020 12:13:05
	(b) (4), (b) (6)	

US3522109

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 16:12:21
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 12:13:05

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

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 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '08:50'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '13 Aug 2020 08:50'	System	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'ONCE'	System	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 12:57:40

US3522109

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:13:36

US3522109

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:13:36

US3522109

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '08:10'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:13:36

US3522109

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '13 Aug 2020 08:10'	System	13 Aug 2020 12:13:36

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:01:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '08:20'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '13 Aug 2020 08:20'	System	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered empty.	System	13 Aug 2020 12:23:34

US3522109

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:23:39

US3522109

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	13 Aug 2020 12:23:39

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:24:41', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c38ccb4e-7d15-46c7-bc80-f48e09c1905d' User entered 'Yes (Y)'	System	13 Aug 2020 13:25:08
	System	13 Aug 2020 13:25:08

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:24:47', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c38ccb4e-7d15-46c7-bc80-f48e09c1905d' User entered '98.0'	System	13 Aug 2020 13:25:08
	System	13 Aug 2020 13:25:08

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:24:51', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c38ccb4e-7d15-46c7-bc80-f48e09c1905d'	System	13 Aug 2020 13:25:08
User entered 'No (N)'	System	13 Aug 2020 13:25:08

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:25:07', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c38ccb4e-7d15-46c7-bc80-f48e09c1905d'	System	13 Aug 2020 13:25:08
User entered '13 Aug 2020 09:25'	System	13 Aug 2020 13:25:08

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 09:10'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 11:40'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:00:27', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd56967c7-f63c-4e80-a951-9462ac6167d4' User entered 'Yes (Y)'	System	13 Aug 2020 23:00:54
	System	13 Aug 2020 23:00:54

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:00:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd56967c7-f63c-4e80-a951-9462ac6167d4' User entered '98.1'	System	13 Aug 2020 23:00:54
	System	13 Aug 2020 23:00:54

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:00:36', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd56967c7-f63c-4e80-a951-9462ac6167d4' User entered 'Yes (Y)'	System	13 Aug 2020 23:00:54
	System	13 Aug 2020 23:00:54

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'had slight pain, took naproxen (see line 1 in com. meds) which was already prescribed for generalized pain and taken as needed.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 02:26:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:00:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd56967c7-f63c-4e80-a951-9462ac6167d4' User entered '1'	Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:08:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Aug 2020 23:00:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:00:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd56967c7-f63c-4e80-a951-9462ac6167d4' User entered '1'	System	13 Aug 2020 23:00:54
User entered '1'	System	13 Aug 2020 23:00:54

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:00:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd56967c7-f63c-4e80-a951-9462ac6167d4' User entered '0'	System	13 Aug 2020 23:00:54
	System	13 Aug 2020 23:00:54

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:00:53', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd56967c7-f63c-4e80-a951-9462ac6167d4'	System	13 Aug 2020 23:00:54
User entered '13 Aug 2020 19:00'	System	13 Aug 2020 23:00:54

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 12:35'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 2'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:50:03', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '58bad5e1-d3a9-44a8-8e05-976436876701' User entered 'Yes (Y)'	System	14 Aug 2020 21:50:19
	System	14 Aug 2020 21:50:19

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:50:08', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '58bad5e1-d3a9-44a8-8e05-976436876701' User entered '97.8'	System	14 Aug 2020 21:50:19
	System	14 Aug 2020 21:50:19

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:50:12', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '58bad5e1-d3a9-44a8-8e05-976436876701' User entered 'No (N)'	System	14 Aug 2020 21:50:19
	System	14 Aug 2020 21:50:19

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:50:16', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '58bad5e1-d3a9-44a8-8e05-976436876701' User entered '14 Aug 2020 17:50'	System	14 Aug 2020 21:50:19
	System	14 Aug 2020 21:50:19

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 3'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:51:47', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c98a3d80-ab4f-4c79-ad17-99c922bfb040' User entered 'Yes (Y)'	System	16 Aug 2020 01:52:06
	System	16 Aug 2020 01:52:06

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:51:52', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c98a3d80-ab4f-4c79-ad17-99c922bfb040' User entered '98.6'	System	16 Aug 2020 01:52:06
	System	16 Aug 2020 01:52:06

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:51:57', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c98a3d80-ab4f-4c79-ad17-99c922bfb040'	System	16 Aug 2020 01:52:06
User entered 'No (N)'	System	16 Aug 2020 01:52:06

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:52:02', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c98a3d80-ab4f-4c79-ad17-99c922bfb040'	System	16 Aug 2020 01:52:06
User entered '15 Aug 2020 21:52'	System	16 Aug 2020 01:52:06

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 4'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:14:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '165c4828-3e28-46e2-8516-2f1ecc38cc4e' User entered 'Yes (Y)'	System	17 Aug 2020 10:15:15
	System	17 Aug 2020 10:15:15

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:03', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '165c4828-3e28-46e2-8516-2f1ecc38cc4e' User entered '98.1'	System	17 Aug 2020 10:15:15
	System	17 Aug 2020 10:15:15

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:08', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '165c4828-3e28-46e2-8516-2f1ecc38cc4e' User entered 'No (N)'	System	17 Aug 2020 10:15:15
	System	17 Aug 2020 10:15:15

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:14', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '165c4828-3e28-46e2-8516-2f1ecc38cc4e' User entered '17 Aug 2020 06:15'	System	17 Aug 2020 10:15:15
	System	17 Aug 2020 10:15:15

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 5'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:09:25', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'be8709a5-e88c-4059-b2e9-445e82d433fc' User entered 'Yes (Y)'	System	18 Aug 2020 08:09:44
	System	18 Aug 2020 08:09:44

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:09:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'be8709a5-e88c-4059-b2e9-445e82d433fc' User entered '98.3'	System	18 Aug 2020 08:09:44
	System	18 Aug 2020 08:09:44

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:09:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'be8709a5-e88c-4059-b2e9-445e82d433fc'	System	18 Aug 2020 08:09:44
User entered 'No (N)'	System	18 Aug 2020 08:09:44

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:09:38', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'be8709a5-e88c-4059-b2e9-445e82d433fc' User entered '18 Aug 2020 04:09'	System	18 Aug 2020 08:09:44
	System	18 Aug 2020 08:09:44

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 6'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:00:51', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'bba71f9f-8d20-4e8a-a838-b176077ad14f' User entered 'Yes (Y)'	System	19 Aug 2020 11:01:08
	System	19 Aug 2020 11:01:08

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:00:57', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'bba71f9f-8d20-4e8a-a838-b176077ad14f' User entered '97.9'	System	19 Aug 2020 11:01:08
	System	19 Aug 2020 11:01:08

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'bba71f9f-8d20-4e8a-a838-b176077ad14f' User entered 'No (N)'	System	19 Aug 2020 11:01:08
	System	19 Aug 2020 11:01:08

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:07', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'bba71f9f-8d20-4e8a-a838-b176077ad14f' User entered '19 Aug 2020 07:01'	System	19 Aug 2020 11:01:08
	System	19 Aug 2020 11:01:08

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 7'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:10', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c07bd8e7-fb9f-4236-8ce5-3510ce611006' User entered 'Yes (Y)'	System	20 Aug 2020 13:36:25
	System	20 Aug 2020 13:36:25

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:14', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c07bd8e7-fb9f-4236-8ce5-3510ce611006' User entered '98.0'	System	20 Aug 2020 13:36:25
	System	20 Aug 2020 13:36:25

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:17', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c07bd8e7-fb9f-4236-8ce5-3510ce611006'	System	20 Aug 2020 13:36:25
User entered 'No (N)'	System	20 Aug 2020 13:36:25

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:21', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c07bd8e7-fb9f-4236-8ce5-3510ce611006'	System	20 Aug 2020 13:36:25
User entered '20 Aug 2020 09:36'	System	20 Aug 2020 13:36:25

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:25:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '26e88cec-0242-41e2-b665-7af7423613c9'	System	13 Aug 2020 13:25:59
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 13:25:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:25:37', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '26e88cec-0242-41e2-b665-7af7423613c9' User entered 'No (N)'	System	13 Aug 2020 13:25:59
	System	13 Aug 2020 13:25:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:25:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '26e88cec-0242-41e2-b665-7af7423613c9' User entered 'No (N)'	System	13 Aug 2020 13:25:59
	System	13 Aug 2020 13:25:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:25:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '26e88cec-0242-41e2-b665-7af7423613c9' User entered 'None (1)'	System	13 Aug 2020 13:25:59
	System	13 Aug 2020 13:25:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:25:57', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '26e88cec-0242-41e2-b665-7af7423613c9' User entered '13 Aug 2020 09:25'	System	13 Aug 2020 13:25:59
	System	13 Aug 2020 13:25:59

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 09:10'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 11:40'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:14', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '6930152d-1320-4de6-ab5f-026fcc143ad9'	System	13 Aug 2020 23:02:19
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 23:02:19

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:01:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '6930152d-1320-4de6-ab5f-026fcc143ad9' User entered 'No (N)'	System	13 Aug 2020 23:02:19
	System	13 Aug 2020 23:02:19

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:01:44', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '6930152d-1320-4de6-ab5f-026fcc143ad9' User entered 'No (N)'	System	13 Aug 2020 23:02:19
	System	13 Aug 2020 23:02:19

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:01:54', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '6930152d-1320-4de6-ab5f-026fcc143ad9'	System	13 Aug 2020 23:02:19
User entered 'None (1)'	System	13 Aug 2020 23:02:19

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:17', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '6930152d-1320-4de6-ab5f-026fcc143ad9' User entered '13 Aug 2020 19:02'	System	13 Aug 2020 23:02:19
	System	13 Aug 2020 23:02:19

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 12:35'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 2'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:50:26', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '62e4d5b9-74bf-463e-a497-e308810936bf' User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 21:52:25
	System	14 Aug 2020 21:52:25

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:50:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '62e4d5b9-74bf-463e-a497-e308810936bf' User entered 'Yes (Y)'	System	14 Aug 2020 21:52:25
	System	14 Aug 2020 21:52:25

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:51:03', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '62e4d5b9-74bf-463e-a497-e308810936bf' User entered '3'	System	14 Aug 2020 21:52:25
	System	14 Aug 2020 21:52:25

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:51:06', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '62e4d5b9-74bf-463e-a497-e308810936bf' User entered 'Yes (Y)'	System	14 Aug 2020 21:52:25
	System	14 Aug 2020 21:52:25

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:16', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '62e4d5b9-74bf-463e-a497-e308810936bf' User entered '5'	System	14 Aug 2020 21:52:25
	System	14 Aug 2020 21:52:25

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:51:15', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '62e4d5b9-74bf-463e-a497-e308810936bf' User entered 'None (1)'	System	14 Aug 2020 21:52:25
	System	14 Aug 2020 21:52:25

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:21', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '62e4d5b9-74bf-463e-a497-e308810936bf' User entered '14 Aug 2020 17:52'	System	14 Aug 2020 21:52:25
	System	14 Aug 2020 21:52:25

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 3'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:52:30', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9ad8a20d-b394-454f-a8dd-d43a506453a3'	System	16 Aug 2020 01:52:56
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 01:52:56

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:52:38', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9ad8a20d-b394-454f-a8dd-d43a506453a3' User entered 'No (N)'	System	16 Aug 2020 01:52:56
	System	16 Aug 2020 01:52:56

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:52:41', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9ad8a20d-b394-454f-a8dd-d43a506453a3' User entered 'Yes (Y)'	System	16 Aug 2020 01:52:56
	System	16 Aug 2020 01:52:56

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:52:45', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9ad8a20d-b394-454f-a8dd-d43a506453a3' User entered '6'	System	16 Aug 2020 01:52:56
	System	16 Aug 2020 01:52:56

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:52:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9ad8a20d-b394-454f-a8dd-d43a506453a3' User entered 'None (1)'	System	16 Aug 2020 01:52:56
	System	16 Aug 2020 01:52:56

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:52:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9ad8a20d-b394-454f-a8dd-d43a506453a3'	System	16 Aug 2020 01:52:56
User entered '15 Aug 2020 21:52'	System	16 Aug 2020 01:52:56

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 4'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:20', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'eee6c032-ace4-43c0-a5e1-2956cd163c8b' User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 10:15:41
	System	17 Aug 2020 10:15:41

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:24', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'eee6c032-ace4-43c0-a5e1-2956cd163c8b' User entered 'No (N)'	System	17 Aug 2020 10:15:41
	System	17 Aug 2020 10:15:41

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:28', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'eee6c032-ace4-43c0-a5e1-2956cd163c8b' User entered 'Yes (Y)'	System	17 Aug 2020 10:15:41
	System	17 Aug 2020 10:15:41

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'eee6c032-ace4-43c0-a5e1-2956cd163c8b' User entered '3'	System	17 Aug 2020 10:15:41
	System	17 Aug 2020 10:15:41

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:36', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'eee6c032-ace4-43c0-a5e1-2956cd163c8b' User entered 'None (1)'	System	17 Aug 2020 10:15:41
	System	17 Aug 2020 10:15:41

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'eee6c032-ace4-43c0-a5e1-2956cd163c8b' User entered '17 Aug 2020 06:15'	System	17 Aug 2020 10:15:41
	System	17 Aug 2020 10:15:41

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 5'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:09:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'baf2a7c6-b8df-461c-8d7d-4ce08df5fe73'	System	18 Aug 2020 08:10:27
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 08:10:27

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:09:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'baf2a7c6-b8df-461c-8d7d-4ce08df5fe73'	System	18 Aug 2020 08:10:27
User entered 'No (N)'	System	18 Aug 2020 08:10:27

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:09:51', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'baf2a7c6-b8df-461c-8d7d-4ce08df5fe73'	System	18 Aug 2020 08:10:27
User entered 'Yes (Y)'	System	18 Aug 2020 08:10:27

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:17', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'baf2a7c6-b8df-461c-8d7d-4ce08df5fe73' User entered '2'	System	18 Aug 2020 08:10:27
	System	18 Aug 2020 08:10:27

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:21', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'baf2a7c6-b8df-461c-8d7d-4ce08df5fe73'	System	18 Aug 2020 08:10:27
User entered 'None (1)'	System	18 Aug 2020 08:10:27

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:25', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'baf2a7c6-b8df-461c-8d7d-4ce08df5fe73'	System	18 Aug 2020 08:10:27
User entered '18 Aug 2020 04:10'	System	18 Aug 2020 08:10:27

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 6'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:13', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '95b9a7ef-bf2e-47a4-85c1-c8d8e03d52a9' User entered 'None (1)'	System	19 Aug 2020 11:01:29
	System	19 Aug 2020 11:01:29

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:17', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '95b9a7ef-bf2e-47a4-85c1-c8d8e03d52a9' User entered 'No (N)'	System	19 Aug 2020 11:01:29
	System	19 Aug 2020 11:01:29

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:20', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '95b9a7ef-bf2e-47a4-85c1-c8d8e03d52a9' User entered 'No (N)'	System	19 Aug 2020 11:01:29
	System	19 Aug 2020 11:01:29

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:23', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '95b9a7ef-bf2e-47a4-85c1-c8d8e03d52a9' User entered 'None (1)'	System	19 Aug 2020 11:01:29
	System	19 Aug 2020 11:01:29

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:27', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '95b9a7ef-bf2e-47a4-85c1-c8d8e03d52a9' User entered '19 Aug 2020 07:01'	System	19 Aug 2020 11:01:29
	System	19 Aug 2020 11:01:29

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 7'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:24', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b454b541-c664-4961-8003-57ed0ccc10b8' User entered 'None (1)'	System	20 Aug 2020 13:36:43
	System	20 Aug 2020 13:36:43

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:28', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b454b541-c664-4961-8003-57ed0ccc10b8' User entered 'No (N)'	System	20 Aug 2020 13:36:43
	System	20 Aug 2020 13:36:43

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b454b541-c664-4961-8003-57ed0ccc10b8' User entered 'No (N)'	System	20 Aug 2020 13:36:43
	System	20 Aug 2020 13:36:43

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b454b541-c664-4961-8003-57ed0ccc10b8' User entered 'None (1)'	System	20 Aug 2020 13:36:43
	System	20 Aug 2020 13:36:43

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b454b541-c664-4961-8003-57ed0ccc10b8' User entered '20 Aug 2020 09:36'	System	20 Aug 2020 13:36:43
	System	20 Aug 2020 13:36:43

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:26:22', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1b0e227f-99d3-42c3-b65e-c686e115f08c' User entered 'None (0)'	System	13 Aug 2020 13:26:57
	System	13 Aug 2020 13:26:57

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:26:28', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1b0e227f-99d3-42c3-b65e-c686e115f08c' User entered 'None (0)'	System	13 Aug 2020 13:26:57
	System	13 Aug 2020 13:26:57

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:26:30', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1b0e227f-99d3-42c3-b65e-c686e115f08c' User entered 'None (0)'	System	13 Aug 2020 13:26:57
	System	13 Aug 2020 13:26:57

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:26:36', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1b0e227f-99d3-42c3-b65e-c686e115f08c' User entered 'None (0)'	System	13 Aug 2020 13:26:57
	System	13 Aug 2020 13:26:57

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:26:38', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1b0e227f-99d3-42c3-b65e-c686e115f08c' User entered 'None (0)'	System	13 Aug 2020 13:26:57
	System	13 Aug 2020 13:26:57

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:26:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1b0e227f-99d3-42c3-b65e-c686e115f08c' User entered 'None (0)'	System	13 Aug 2020 13:26:57
	System	13 Aug 2020 13:26:57

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:26:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1b0e227f-99d3-42c3-b65e-c686e115f08c' User entered 'No (N)'	System	13 Aug 2020 13:26:57
	System	13 Aug 2020 13:26:57

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T09:26:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1b0e227f-99d3-42c3-b65e-c686e115f08c' User entered '13 Aug 2020 09:26'	System	13 Aug 2020 13:26:57
	System	13 Aug 2020 13:26:57

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 09:10'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 11:40'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:27', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '232d5434-9841-476d-b971-c2242937b04d' User entered 'None (0)'	System	13 Aug 2020 23:03:02
	System	13 Aug 2020 23:03:02

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:32', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '232d5434-9841-476d-b971-c2242937b04d' User entered 'None (0)'	System	13 Aug 2020 23:03:02
	System	13 Aug 2020 23:03:02

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:43', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '232d5434-9841-476d-b971-c2242937b04d' User entered 'None (0)'	System	13 Aug 2020 23:03:02
	System	13 Aug 2020 23:03:02

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:47', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '232d5434-9841-476d-b971-c2242937b04d' User entered 'None (0)'	System	13 Aug 2020 23:03:02
	System	13 Aug 2020 23:03:02

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '232d5434-9841-476d-b971-c2242937b04d' User entered 'None (0)'	System	13 Aug 2020 23:03:02
	System	13 Aug 2020 23:03:02

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:52', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '232d5434-9841-476d-b971-c2242937b04d' User entered 'None (0)'	System	13 Aug 2020 23:03:02
	System	13 Aug 2020 23:03:02

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:02:57', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '232d5434-9841-476d-b971-c2242937b04d' User entered 'No (N)'	System	13 Aug 2020 23:03:02
	System	13 Aug 2020 23:03:02

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-13T19:03:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '232d5434-9841-476d-b971-c2242937b04d' User entered '13 Aug 2020 19:03'	System	13 Aug 2020 23:03:02
	System	13 Aug 2020 23:03:02

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '13 Aug 2020 12:35'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 2'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:26', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c6695d6e-9c7b-4ebb-9343-a543462909f7' User entered 'None (0)'	System	14 Aug 2020 21:52:44
	System	14 Aug 2020 21:52:44

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:28', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c6695d6e-9c7b-4ebb-9343-a543462909f7' User entered 'None (0)'	System	14 Aug 2020 21:52:44
	System	14 Aug 2020 21:52:44

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:30', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c6695d6e-9c7b-4ebb-9343-a543462909f7' User entered 'None (0)'	System	14 Aug 2020 21:52:44
	System	14 Aug 2020 21:52:44

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:32', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c6695d6e-9c7b-4ebb-9343-a543462909f7' User entered 'None (0)'	System	14 Aug 2020 21:52:44
	System	14 Aug 2020 21:52:44

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c6695d6e-9c7b-4ebb-9343-a543462909f7' User entered 'None (0)'	System	14 Aug 2020 21:52:44
	System	14 Aug 2020 21:52:44

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:36', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c6695d6e-9c7b-4ebb-9343-a543462909f7' User entered 'None (0)'	System	14 Aug 2020 21:52:44
	System	14 Aug 2020 21:52:44

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c6695d6e-9c7b-4ebb-9343-a543462909f7'	System	14 Aug 2020 21:52:44
User entered 'No (N)'	System	14 Aug 2020 21:52:44

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-14T17:52:41', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c6695d6e-9c7b-4ebb-9343-a543462909f7'	System	14 Aug 2020 21:52:44
User entered '14 Aug 2020 17:52'	System	14 Aug 2020 21:52:44

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 3'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:53:01', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48dc6b1b-811e-458e-aecf-9f2893c99071' User entered 'None (0)'	System	16 Aug 2020 01:53:38
	System	16 Aug 2020 01:53:38

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:53:04', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48dc6b1b-811e-458e-aecf-9f2893c99071' User entered 'None (0)'	System	16 Aug 2020 01:53:38
	System	16 Aug 2020 01:53:38

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:53:07', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48dc6b1b-811e-458e-aecf-9f2893c99071' User entered 'None (0)'	System	16 Aug 2020 01:53:38
	System	16 Aug 2020 01:53:38

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:53:10', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48dc6b1b-811e-458e-aecf-9f2893c99071' User entered 'None (0)'	System	16 Aug 2020 01:53:38
	System	16 Aug 2020 01:53:38

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:53:13', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48dc6b1b-811e-458e-aecf-9f2893c99071' User entered 'None (0)'	System	16 Aug 2020 01:53:38
	System	16 Aug 2020 01:53:38

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:53:19', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48dc6b1b-811e-458e-aecf-9f2893c99071' User entered 'None (0)'	System	16 Aug 2020 01:53:38
	System	16 Aug 2020 01:53:38

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:53:30', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48dc6b1b-811e-458e-aecf-9f2893c99071' User entered 'No (N)'	System	16 Aug 2020 01:53:38
	System	16 Aug 2020 01:53:38

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-15T21:53:33', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48dc6b1b-811e-458e-aecf-9f2893c99071'	System	16 Aug 2020 01:53:38
User entered '15 Aug 2020 21:53'	System	16 Aug 2020 01:53:38

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 4'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:47', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '758827c5-43c4-4b3b-949f-3d9756bdf501'	System	17 Aug 2020 10:16:10
User entered 'No interference with activity (1)'	System	17 Aug 2020 10:16:10

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '758827c5-43c4-4b3b-949f-3d9756bdf501' User entered 'None (0)'	System	17 Aug 2020 10:16:10
	System	17 Aug 2020 10:16:10

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:53', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '758827c5-43c4-4b3b-949f-3d9756bdf501' User entered 'None (0)'	System	17 Aug 2020 10:16:10
	System	17 Aug 2020 10:16:10

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:56', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '758827c5-43c4-4b3b-949f-3d9756bdf501' User entered 'None (0)'	System	17 Aug 2020 10:16:10
	System	17 Aug 2020 10:16:10

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:15:59', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '758827c5-43c4-4b3b-949f-3d9756bdf501' User entered 'None (0)'	System	17 Aug 2020 10:16:10
	System	17 Aug 2020 10:16:10

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:16:01', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '758827c5-43c4-4b3b-949f-3d9756bdf501' User entered 'None (0)'	System	17 Aug 2020 10:16:10
	System	17 Aug 2020 10:16:10

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:16:05', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '758827c5-43c4-4b3b-949f-3d9756bdf501' User entered 'No (N)'	System	17 Aug 2020 10:16:10
	System	17 Aug 2020 10:16:10

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-17T06:16:08', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '758827c5-43c4-4b3b-949f-3d9756bdf501'	System	17 Aug 2020 10:16:10
User entered '17 Aug 2020 06:16'	System	17 Aug 2020 10:16:10

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 5'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:30', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '36eb9442-77ca-4351-95ab-85d9d1cb7fb0' User entered 'None (0)'	System	18 Aug 2020 08:10:48
	System	18 Aug 2020 08:10:48

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:33', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '36eb9442-77ca-4351-95ab-85d9d1cb7fb0' User entered 'None (0)'	System	18 Aug 2020 08:10:48
	System	18 Aug 2020 08:10:48

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:35', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '36eb9442-77ca-4351-95ab-85d9d1cb7fb0' User entered 'None (0)'	System	18 Aug 2020 08:10:48
	System	18 Aug 2020 08:10:48

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:37', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '36eb9442-77ca-4351-95ab-85d9d1cb7fb0' User entered 'None (0)'	System	18 Aug 2020 08:10:48
	System	18 Aug 2020 08:10:48

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '36eb9442-77ca-4351-95ab-85d9d1cb7fb0' User entered 'None (0)'	System	18 Aug 2020 08:10:48
	System	18 Aug 2020 08:10:48

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:41', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '36eb9442-77ca-4351-95ab-85d9d1cb7fb0' User entered 'None (0)'	System	18 Aug 2020 08:10:48
	System	18 Aug 2020 08:10:48

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:44', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '36eb9442-77ca-4351-95ab-85d9d1cb7fb0'	System	18 Aug 2020 08:10:48
User entered 'No (N)'	System	18 Aug 2020 08:10:48

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-18T04:10:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '36eb9442-77ca-4351-95ab-85d9d1cb7fb0' User entered '18 Aug 2020 04:10'	System	18 Aug 2020 08:10:48
	System	18 Aug 2020 08:10:48

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 6'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1978d21c-39d9-4ca8-8d49-e69e0b013bf0' User entered 'None (0)'	System	19 Aug 2020 11:01:52
	System	19 Aug 2020 11:01:52

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1978d21c-39d9-4ca8-8d49-e69e0b013bf0' User entered 'None (0)'	System	19 Aug 2020 11:01:52
	System	19 Aug 2020 11:01:52

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:35', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1978d21c-39d9-4ca8-8d49-e69e0b013bf0' User entered 'None (0)'	System	19 Aug 2020 11:01:52
	System	19 Aug 2020 11:01:52

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:38', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1978d21c-39d9-4ca8-8d49-e69e0b013bf0' User entered 'None (0)'	System	19 Aug 2020 11:01:52
	System	19 Aug 2020 11:01:52

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1978d21c-39d9-4ca8-8d49-e69e0b013bf0' User entered 'None (0)'	System	19 Aug 2020 11:01:52
	System	19 Aug 2020 11:01:52

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:42', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1978d21c-39d9-4ca8-8d49-e69e0b013bf0' User entered 'None (0)'	System	19 Aug 2020 11:01:52
	System	19 Aug 2020 11:01:52

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:47', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1978d21c-39d9-4ca8-8d49-e69e0b013bf0' User entered 'No (N)'	System	19 Aug 2020 11:01:52
	System	19 Aug 2020 11:01:52

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-19T07:01:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1978d21c-39d9-4ca8-8d49-e69e0b013bf0' User entered '19 Aug 2020 07:01'	System	19 Aug 2020 11:01:52
	System	19 Aug 2020 11:01:52

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 7'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:43', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2eb1ca70-0469-4ca0-86ec-abe98f6c53db' User entered 'None (0)'	System	20 Aug 2020 13:37:03
	System	20 Aug 2020 13:37:03

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:45', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2eb1ca70-0469-4ca0-86ec-abe98f6c53db' User entered 'None (0)'	System	20 Aug 2020 13:37:03
	System	20 Aug 2020 13:37:03

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:48', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2eb1ca70-0469-4ca0-86ec-abe98f6c53db' User entered 'None (0)'	System	20 Aug 2020 13:37:03
	System	20 Aug 2020 13:37:03

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2eb1ca70-0469-4ca0-86ec-abe98f6c53db' User entered 'None (0)'	System	20 Aug 2020 13:37:03
	System	20 Aug 2020 13:37:03

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:52', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2eb1ca70-0469-4ca0-86ec-abe98f6c53db' User entered 'None (0)'	System	20 Aug 2020 13:37:03
	System	20 Aug 2020 13:37:03

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:53', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2eb1ca70-0469-4ca0-86ec-abe98f6c53db' User entered 'None (0)'	System	20 Aug 2020 13:37:03
	System	20 Aug 2020 13:37:03

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

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 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:36:56', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2eb1ca70-0469-4ca0-86ec-abe98f6c53db' User entered 'No (N)'	System	20 Aug 2020 13:37:03
	System	20 Aug 2020 13:37:03

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-08-20T09:37:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2eb1ca70-0469-4ca0-86ec-abe98f6c53db' User entered '20 Aug 2020 09:37'	System	20 Aug 2020 13:37:03
	System	20 Aug 2020 13:37:03

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 12:57:40

US3522109

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	20 Aug 2020 13:27:35

US3522109

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '20 Aug 2020'	Yaman Ahmed (b) (4)	20 Aug 2020 13:27:35

US3522109

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	20 Aug 2020 13:27:35

US3522109

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'prescription Naproxen taken on Day 1-2 for pain, redness and swelling symptoms, which resolved by day 7. Recorded swelling/hardness in cm instead of mm in e-diary. Otherwise no other changes reported'	Yaman Ahmed (b) (4)	20 Aug 2020 13:27:35

US3522109

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	20 Aug 2020 13:27:44

US3522109

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	20 Aug 2020 13:27:44

US3522109

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	27 Aug 2020 16:26:51

US3522109

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '27 Aug 2020'	Yaman Ahmed (b) (4)	27 Aug 2020 16:26:51

US3522109

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	27 Aug 2020 16:26:51

US3522109

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, or Covid-19 exposure risk'	Yaman Ahmed (b) (4)	27 Aug 2020 16:26:51

US3522109

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	27 Aug 2020 16:26:57

US3522109

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	27 Aug 2020 16:26:57

US3522109

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	03 Sep 2020 18:01:18

US3522109

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '3 Sep 2020'	Yaman Ahmed (b) (4)	03 Sep 2020 18:01:18

US3522109

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	03 Sep 2020 18:39:09
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	Yaman Ahmed (b) (4)	03 Sep 2020 18:01:18
	(b) (4)	

US3522109

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
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: New Information	(b) (4) Yaman Ahmed (b) (4)	03 Sep 2020 18:39:09
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	03 Sep 2020 18:01:18

US3522109

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	03 Sep 2020 18:39:14

US3522109

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	03 Sep 2020 18:39:14

US3522109

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:41:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:41:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[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 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:41:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'VISIT2'	System	10 Sep 2020 11:41:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '07:44'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '10 Sep 2020 07:44'	System	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '73'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'bpm'	System	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'breaths/min'	System	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '139'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '83'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	10 Sep 2020 11:49:10

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '09:12'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '10 Sep 2020 09:12'	System	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 13:12:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 13:12:35
User entered '97.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:12:35
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:11:02
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 13:12:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 13:12:35
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:12:35
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:11:02
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'bpm'	System	10 Sep 2020 13:12:35
User entered empty.	System	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 13:12:35
Query 'Data is required. Please provide.' answered by System	System	10 Sep 2020 13:12:35
data change (Site from System).		
User entered '12' reason for change: Data Entry	(b) (4), (b) (6)	10 Sep 2020 13:12:35
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:11:02
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'breaths/min'	System	10 Sep 2020 13:12:35
User entered empty.	System	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	10 Sep 2020 13:12:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Sep 2020 13:12:35
User entered '138' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:12:35
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:11:02
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	10 Sep 2020 13:12:35
User entered empty.	System	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 13:12:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 13:12:35
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 13:12:35
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 13:11:02
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	10 Sep 2020 13:12:35
User entered empty.	System	10 Sep 2020 13:11:02

US3522109

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:41:12

US3522109

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:41:12

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

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 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '08:42'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '10 Sep 2020 08:42'	System	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'ONCE'	System	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:01:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 12:48:05

US3522109

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:21

US3522109

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:21

US3522109

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '7:55'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:21

US3522109

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '10 Sep 2020 7:55'	System	10 Sep 2020 12:48:21

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:01:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '07:58'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '10 Sep 2020 07:58'	System	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered empty.	System	10 Sep 2020 12:48:40

US3522109

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 11:41:17

US3522109

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '1'	System	10 Sep 2020 11:41:17

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:09:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1688cecf-a70f-48b1-87fe-cef0c3c8d590' User entered 'Yes (Y)'	System	10 Sep 2020 13:09:52
	System	10 Sep 2020 13:09:52

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:09:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1688cecf-a70f-48b1-87fe-cef0c3c8d590' User entered '97.7'	System	10 Sep 2020 13:09:52
	System	10 Sep 2020 13:09:52

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:09:42', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1688cecf-a70f-48b1-87fe-cef0c3c8d590' User entered 'No (N)'	System	10 Sep 2020 13:09:52
	System	10 Sep 2020 13:09:52

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:09:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1688cecf-a70f-48b1-87fe-cef0c3c8d590' User entered '10 Sep 2020 09:09'	System	10 Sep 2020 13:09:52
	System	10 Sep 2020 13:09:52

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 09:02'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 11:32'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T20:55:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b615cf66-4839-4099-93dc-ee1199649955' User entered 'Yes (Y)'	System	11 Sep 2020 00:55:57
	System	11 Sep 2020 00:55:57

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T20:55:47', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b615cf66-4839-4099-93dc-ee1199649955' User entered '97.6'	System	11 Sep 2020 00:55:57
	System	11 Sep 2020 00:55:57

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T20:55:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b615cf66-4839-4099-93dc-ee1199649955'	System	11 Sep 2020 00:55:57
User entered 'No (N)'	System	11 Sep 2020 00:55:57

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T20:55:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b615cf66-4839-4099-93dc-ee1199649955'	System	11 Sep 2020 00:55:57
User entered '10 Sep 2020 20:55'	System	11 Sep 2020 00:55:57

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 12:27'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 2'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:31:35', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '173bfc9e-e14f-4df7-a2b6-8a81abf93baa'	System	11 Sep 2020 17:32:03
User entered 'Yes (Y)'	System	11 Sep 2020 17:32:03

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:31:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '173bfc9e-e14f-4df7-a2b6-8a81abf93baa' User entered '99.0'	System	11 Sep 2020 17:32:03
	System	11 Sep 2020 17:32:03

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:31:44', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '173bfc9e-e14f-4df7-a2b6-8a81abf93baa'	System	11 Sep 2020 17:32:03
User entered 'Yes (Y)'	System	11 Sep 2020 17:32:03

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pt took naproxen 500mg (prescribed for her knee arthritis) for pain at injection site and in knee ' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:34:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alandra White (b) (4)	23 Oct 2020 18:58:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:31:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '173bfc9e-e14f-4df7-a2b6-8a81abf93baa'	System	11 Sep 2020 17:32:03
User entered '1'	System	11 Sep 2020 17:32:03

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:31:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '173bfc9e-e14f-4df7-a2b6-8a81abf93baa' User entered '0'	System	11 Sep 2020 17:32:03
	System	11 Sep 2020 17:32:03

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:31:54', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '173bfc9e-e14f-4df7-a2b6-8a81abf93baa'	System	11 Sep 2020 17:32:03
User entered '11 Sep 2020 13:31'	System	11 Sep 2020 17:32:03

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 3'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:01:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ab2eb3d5-69c5-41c8-830a-5562bcfa0a99'	System	12 Sep 2020 23:01:55
User entered 'Yes (Y)'	System	12 Sep 2020 23:01:55

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:01:44', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ab2eb3d5-69c5-41c8-830a-5562bcfa0a99' User entered '97.5'	System	12 Sep 2020 23:01:55
	System	12 Sep 2020 23:01:55

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:01:48', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ab2eb3d5-69c5-41c8-830a-5562bcfa0a99'	System	12 Sep 2020 23:01:55
User entered 'No (N)'	System	12 Sep 2020 23:01:55

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:01:53', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ab2eb3d5-69c5-41c8-830a-5562bcfa0a99'	System	12 Sep 2020 23:01:55
User entered '12 Sep 2020 19:01'	System	12 Sep 2020 23:01:55

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 4'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:49:48', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1e6d0268-3e89-48ab-9be1-2bbd1fa7d21c' User entered 'Yes (Y)'	System	14 Sep 2020 00:50:07
	System	14 Sep 2020 00:50:07

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:49:52', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1e6d0268-3e89-48ab-9be1-2bbd1fa7d21c' User entered '99.4'	System	14 Sep 2020 00:50:07
	System	14 Sep 2020 00:50:07

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:49:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1e6d0268-3e89-48ab-9be1-2bbd1fa7d21c' User entered 'Yes (Y)'	System	14 Sep 2020 00:50:07
	System	14 Sep 2020 00:50:07

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pt took naproxen 500mg (prescribed for her knee arthritis) for pain at injection site and in knee ' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:34:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:02', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1e6d0268-3e89-48ab-9be1-2bbd1fa7d21c' User entered '1'	Alandra White (b) (4) (b) (4)	23 Oct 2020 18:58:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Sep 2020 00:50:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:02', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1e6d0268-3e89-48ab-9be1-2bbd1fa7d21c' User entered '1'	System	14 Sep 2020 00:50:07
User entered '1'	System	14 Sep 2020 00:50:07

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:02', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1e6d0268-3e89-48ab-9be1-2bbd1fa7d21c' User entered '0'	System	14 Sep 2020 00:50:07
	System	14 Sep 2020 00:50:07

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:05', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '1e6d0268-3e89-48ab-9be1-2bbd1fa7d21c'	System	14 Sep 2020 00:50:07
User entered '13 Sep 2020 20:50'	System	14 Sep 2020 00:50:07

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 5'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:30:35', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48775de5-828b-41ce-aa43-fc64c7eec493' User entered 'Yes (Y)'	System	15 Sep 2020 02:30:52
	System	15 Sep 2020 02:30:52

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:30:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48775de5-828b-41ce-aa43-fc64c7eec493' User entered '98.3'	System	15 Sep 2020 02:30:52
	System	15 Sep 2020 02:30:52

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:30:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48775de5-828b-41ce-aa43-fc64c7eec493'	System	15 Sep 2020 02:30:52
User entered 'No (N)'	System	15 Sep 2020 02:30:52

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:30:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '48775de5-828b-41ce-aa43-fc64c7eec493'	System	15 Sep 2020 02:30:52
User entered '14 Sep 2020 22:30'	System	15 Sep 2020 02:30:52

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 6'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'f008f714-1249-456a-80e1-229f13ccba19' User entered 'Yes (Y)'	System	16 Sep 2020 01:35:20
	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:04', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'f008f714-1249-456a-80e1-229f13ccba19' User entered '98.3'	System	16 Sep 2020 01:35:20
	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:08', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'f008f714-1249-456a-80e1-229f13ccba19'	System	16 Sep 2020 01:35:20
User entered 'Yes (Y)'	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'pt took naproxen 500mg (prescribed for her knee arthritis) for pain at injection site and in knee ' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 08:34:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:12', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'f008f714-1249-456a-80e1-229f13ccba19' User entered '1'	Alandra White (b) (4) (b) (4)	23 Oct 2020 18:58:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Sep 2020 01:35:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:12', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'f008f714-1249-456a-80e1-229f13ccba19' User entered '1'	System	16 Sep 2020 01:35:20
User entered '1'	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:12', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'f008f714-1249-456a-80e1-229f13ccba19' User entered '0'	System	16 Sep 2020 01:35:20
	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:17', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'f008f714-1249-456a-80e1-229f13ccba19' User entered '15 Sep 2020 21:35'	System	16 Sep 2020 01:35:20
	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 7'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	16 Sep 2020 01:35:20
User entered 'Day 8'	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:01:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:24:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ad03cf52-0a62-4a8c-a892-1160f97e1b71' User entered 'Yes (Y)'	System	18 Sep 2020 11:24:59
	System	18 Sep 2020 11:24:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:01:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:24:45', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ad03cf52-0a62-4a8c-a892-1160f97e1b71' User entered '97.4'	System	18 Sep 2020 11:24:59
	System	18 Sep 2020 11:24:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:01:11

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:24:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ad03cf52-0a62-4a8c-a892-1160f97e1b71'	System	18 Sep 2020 11:24:59
User entered 'No (N)'	System	18 Sep 2020 11:24:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:24:54', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ad03cf52-0a62-4a8c-a892-1160f97e1b71' User entered '18 Sep 2020 07:24'	System	18 Sep 2020 11:24:59
	System	18 Sep 2020 11:24:59

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:14', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '01289aeb-5463-4e80-a097-48272467be03'	System	10 Sep 2020 13:05:50
User entered 'None (1)'	System	10 Sep 2020 13:05:50

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:29', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '01289aeb-5463-4e80-a097-48272467be03' User entered 'No (N)'	System	10 Sep 2020 13:05:50
	System	10 Sep 2020 13:05:50

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:37', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '01289aeb-5463-4e80-a097-48272467be03' User entered 'No (N)'	System	10 Sep 2020 13:05:50
	System	10 Sep 2020 13:05:50

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:42', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '01289aeb-5463-4e80-a097-48272467be03'	System	10 Sep 2020 13:05:50
User entered 'None (1)'	System	10 Sep 2020 13:05:50

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '01289aeb-5463-4e80-a097-48272467be03' User entered '10 Sep 2020 09:05'	System	10 Sep 2020 13:05:50
	System	10 Sep 2020 13:05:50

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 09:02'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 11:32'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T20:56:03', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a7b08200-5d3e-4867-972f-fd99187e372d'	System	11 Sep 2020 01:02:09
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 01:02:09

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T20:56:10', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a7b08200-5d3e-4867-972f-fd99187e372d'	System	11 Sep 2020 01:02:09
User entered 'Yes (Y)'	System	11 Sep 2020 01:02:09

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:01:47', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a7b08200-5d3e-4867-972f-fd99187e372d' User entered '5'	System	11 Sep 2020 01:02:09
	System	11 Sep 2020 01:02:09

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:01:52', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a7b08200-5d3e-4867-972f-fd99187e372d' User entered 'No (N)'	System	11 Sep 2020 01:02:09
	System	11 Sep 2020 01:02:09

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:01:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a7b08200-5d3e-4867-972f-fd99187e372d' User entered 'None (1)'	System	11 Sep 2020 01:02:09
	System	11 Sep 2020 01:02:09

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:05', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a7b08200-5d3e-4867-972f-fd99187e372d' User entered '10 Sep 2020 21:02'	System	11 Sep 2020 01:02:09
	System	11 Sep 2020 01:02:09

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 12:27'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 2'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:08', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fefcda6b-53f4-4208-b8f0-5fd39dd3abc8'	System	11 Sep 2020 17:32:46
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 17:32:46

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:11', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fefcda6b-53f4-4208-b8f0-5fd39dd3abc8'	System	11 Sep 2020 17:32:46
User entered 'Yes (Y)'	System	11 Sep 2020 17:32:46

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:21', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fefcda6b-53f4-4208-b8f0-5fd39dd3abc8' User entered '10'	System	11 Sep 2020 17:32:46
	System	11 Sep 2020 17:32:46

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:24', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fefcda6b-53f4-4208-b8f0-5fd39dd3abc8'	System	11 Sep 2020 17:32:46
User entered 'Yes (Y)'	System	11 Sep 2020 17:32:46

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:28', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fefcda6b-53f4-4208-b8f0-5fd39dd3abc8' User entered '60'	System	11 Sep 2020 17:32:46
	System	11 Sep 2020 17:32:46

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fefcda6b-53f4-4208-b8f0-5fd39dd3abc8'	System	11 Sep 2020 17:32:46
User entered 'None (1)'	System	11 Sep 2020 17:32:46

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:44', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fefcda6b-53f4-4208-b8f0-5fd39dd3abc8'	System	11 Sep 2020 17:32:46
User entered '11 Sep 2020 13:32'	System	11 Sep 2020 17:32:46

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 3'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:01:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '87059bac-2407-42c0-a7ce-97459512db43'	System	12 Sep 2020 23:04:04
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 23:04:04

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:02:01', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '87059bac-2407-42c0-a7ce-97459512db43'	System	12 Sep 2020 23:04:04
User entered 'Yes (Y)'	System	12 Sep 2020 23:04:04

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:03:23', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '87059bac-2407-42c0-a7ce-97459512db43' User entered '70'	System	12 Sep 2020 23:04:04
	System	12 Sep 2020 23:04:04

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:03:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '87059bac-2407-42c0-a7ce-97459512db43'	System	12 Sep 2020 23:04:04
User entered 'Yes (Y)'	System	12 Sep 2020 23:04:04

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:03:54', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '87059bac-2407-42c0-a7ce-97459512db43' User entered '95'	System	12 Sep 2020 23:04:04
	System	12 Sep 2020 23:04:04

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '87059bac-2407-42c0-a7ce-97459512db43'	System	12 Sep 2020 23:04:04
User entered 'None (1)'	System	12 Sep 2020 23:04:04

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:03', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '87059bac-2407-42c0-a7ce-97459512db43' User entered '12 Sep 2020 19:04'	System	12 Sep 2020 23:04:04
	System	12 Sep 2020 23:04:04

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 4'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:17', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '40db44b1-6ee4-4aee-b018-b12e68500e9a'	System	14 Sep 2020 00:50:40
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 00:50:40

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:20', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '40db44b1-6ee4-4aee-b018-b12e68500e9a' User entered 'Yes (Y)'	System	14 Sep 2020 00:50:40
	System	14 Sep 2020 00:50:40

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:23', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '40db44b1-6ee4-4aee-b018-b12e68500e9a' User entered '45'	System	14 Sep 2020 00:50:40
	System	14 Sep 2020 00:50:40

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:26', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '40db44b1-6ee4-4aee-b018-b12e68500e9a' User entered 'Yes (Y)'	System	14 Sep 2020 00:50:40
	System	14 Sep 2020 00:50:40

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:29', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '40db44b1-6ee4-4aee-b018-b12e68500e9a' User entered '70'	System	14 Sep 2020 00:50:40
	System	14 Sep 2020 00:50:40

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:35', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '40db44b1-6ee4-4aee-b018-b12e68500e9a' User entered 'None (1)'	System	14 Sep 2020 00:50:40
	System	14 Sep 2020 00:50:40

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:38', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '40db44b1-6ee4-4aee-b018-b12e68500e9a' User entered '13 Sep 2020 20:50'	System	14 Sep 2020 00:50:40
	System	14 Sep 2020 00:50:40

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 5'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:30:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '853bbc7d-bbcb-4962-984e-c369a7d711b1'	System	15 Sep 2020 02:31:22
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 02:31:22

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:30:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '853bbc7d-bbcb-4962-984e-c369a7d711b1' User entered 'Yes (Y)'	System	15 Sep 2020 02:31:22
	System	15 Sep 2020 02:31:22

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:02', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '853bbc7d-bbcb-4962-984e-c369a7d711b1' User entered '60'	System	15 Sep 2020 02:31:22
	System	15 Sep 2020 02:31:22

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:07', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '853bbc7d-bbcb-4962-984e-c369a7d711b1' User entered 'Yes (Y)'	System	15 Sep 2020 02:31:22
	System	15 Sep 2020 02:31:22

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:11', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '853bbc7d-bbcb-4962-984e-c369a7d711b1' User entered '55'	System	15 Sep 2020 02:31:22
	System	15 Sep 2020 02:31:22

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:14', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '853bbc7d-bbcb-4962-984e-c369a7d711b1' User entered 'None (1)'	System	15 Sep 2020 02:31:22
	System	15 Sep 2020 02:31:22

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:19', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '853bbc7d-bbcb-4962-984e-c369a7d711b1' User entered '14 Sep 2020 22:31'	System	15 Sep 2020 02:31:22
	System	15 Sep 2020 02:31:22

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 6'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:25', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5f26c581-32b4-476b-a74e-40128179cf2d' User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 01:35:41
	System	16 Sep 2020 01:35:41

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:27', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5f26c581-32b4-476b-a74e-40128179cf2d' User entered 'No (N)'	System	16 Sep 2020 01:35:41
	System	16 Sep 2020 01:35:41

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:29', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5f26c581-32b4-476b-a74e-40128179cf2d' User entered 'No (N)'	System	16 Sep 2020 01:35:41
	System	16 Sep 2020 01:35:41

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:35', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5f26c581-32b4-476b-a74e-40128179cf2d' User entered 'None (1)'	System	16 Sep 2020 01:35:41
	System	16 Sep 2020 01:35:41

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:38', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5f26c581-32b4-476b-a74e-40128179cf2d' User entered '15 Sep 2020 21:35'	System	16 Sep 2020 01:35:41
	System	16 Sep 2020 01:35:41

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 7'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:51', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd10a339e-ed85-440c-b503-b31b31c262ad' User entered 'None (0)'	System	10 Sep 2020 13:06:16
	System	10 Sep 2020 13:06:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:54', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd10a339e-ed85-440c-b503-b31b31c262ad' User entered 'None (0)'	System	10 Sep 2020 13:06:16
	System	10 Sep 2020 13:06:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:56', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd10a339e-ed85-440c-b503-b31b31c262ad' User entered 'None (0)'	System	10 Sep 2020 13:06:16
	System	10 Sep 2020 13:06:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:05:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd10a339e-ed85-440c-b503-b31b31c262ad' User entered 'None (0)'	System	10 Sep 2020 13:06:16
	System	10 Sep 2020 13:06:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:06:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd10a339e-ed85-440c-b503-b31b31c262ad' User entered 'None (0)'	System	10 Sep 2020 13:06:16
	System	10 Sep 2020 13:06:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:06:02', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd10a339e-ed85-440c-b503-b31b31c262ad' User entered 'None (0)'	System	10 Sep 2020 13:06:16
	System	10 Sep 2020 13:06:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:06:12', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd10a339e-ed85-440c-b503-b31b31c262ad' User entered 'No (N)'	System	10 Sep 2020 13:06:16
	System	10 Sep 2020 13:06:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T09:06:15', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'd10a339e-ed85-440c-b503-b31b31c262ad' User entered '10 Sep 2020 09:06'	System	10 Sep 2020 13:06:16
	System	10 Sep 2020 13:06:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 09:02'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 11:32'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:09', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7ec00b57-6d9f-45df-a28b-2d8e1874b3c6' User entered 'None (0)'	System	11 Sep 2020 01:02:40
	System	11 Sep 2020 01:02:40

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:13', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7ec00b57-6d9f-45df-a28b-2d8e1874b3c6' User entered 'None (0)'	System	11 Sep 2020 01:02:40
	System	11 Sep 2020 01:02:40

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:16', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7ec00b57-6d9f-45df-a28b-2d8e1874b3c6' User entered 'None (0)'	System	11 Sep 2020 01:02:40
	System	11 Sep 2020 01:02:40

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:19', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7ec00b57-6d9f-45df-a28b-2d8e1874b3c6' User entered 'None (0)'	System	11 Sep 2020 01:02:40
	System	11 Sep 2020 01:02:40

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:22', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7ec00b57-6d9f-45df-a28b-2d8e1874b3c6' User entered 'None (0)'	System	11 Sep 2020 01:02:40
	System	11 Sep 2020 01:02:40

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:26', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7ec00b57-6d9f-45df-a28b-2d8e1874b3c6' User entered 'None (0)'	System	11 Sep 2020 01:02:40
	System	11 Sep 2020 01:02:40

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:29', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7ec00b57-6d9f-45df-a28b-2d8e1874b3c6'	System	11 Sep 2020 01:02:40
User entered 'No (N)'	System	11 Sep 2020 01:02:40

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-10T21:02:32', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7ec00b57-6d9f-45df-a28b-2d8e1874b3c6' User entered '10 Sep 2020 21:02'	System	11 Sep 2020 01:02:40
	System	11 Sep 2020 01:02:40

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '10 Sep 2020 12:27'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 2'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5839ac41-9400-46c8-8984-85be3c518c46' User entered 'No interference with activity (1)'	System	11 Sep 2020 17:33:16
	System	11 Sep 2020 17:33:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5839ac41-9400-46c8-8984-85be3c518c46' User entered 'None (0)'	System	11 Sep 2020 17:33:16
	System	11 Sep 2020 17:33:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:32:59', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5839ac41-9400-46c8-8984-85be3c518c46'	System	11 Sep 2020 17:33:16
User entered 'No interference with activity (1)'	System	11 Sep 2020 17:33:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:33:03', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5839ac41-9400-46c8-8984-85be3c518c46'	System	11 Sep 2020 17:33:16
User entered 'No interference with activity (1)'	System	11 Sep 2020 17:33:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:33:05', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5839ac41-9400-46c8-8984-85be3c518c46' User entered 'None (0)'	System	11 Sep 2020 17:33:16
	System	11 Sep 2020 17:33:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:33:07', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5839ac41-9400-46c8-8984-85be3c518c46' User entered 'None (0)'	System	11 Sep 2020 17:33:16
	System	11 Sep 2020 17:33:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:33:09', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5839ac41-9400-46c8-8984-85be3c518c46' User entered 'No (N)'	System	11 Sep 2020 17:33:16
	System	11 Sep 2020 17:33:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-11T13:33:12', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5839ac41-9400-46c8-8984-85be3c518c46' User entered '11 Sep 2020 13:33'	System	11 Sep 2020 17:33:16
	System	11 Sep 2020 17:33:16

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 3'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:06', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdbebefd-0511-4623-b3d1-fd6a979e4118' User entered 'None (0)'	System	12 Sep 2020 23:04:34
	System	12 Sep 2020 23:04:34

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:08', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdbebefd-0511-4623-b3d1-fd6a979e4118' User entered 'None (0)'	System	12 Sep 2020 23:04:34
	System	12 Sep 2020 23:04:34

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:14', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdbebefd-0511-4623-b3d1-fd6a979e4118' User entered 'None (0)'	System	12 Sep 2020 23:04:34
	System	12 Sep 2020 23:04:34

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:16', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdbebefd-0511-4623-b3d1-fd6a979e4118' User entered 'None (0)'	System	12 Sep 2020 23:04:34
	System	12 Sep 2020 23:04:34

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdbebefd-0511-4623-b3d1-fd6a979e4118' User entered 'None (0)'	System	12 Sep 2020 23:04:34
	System	12 Sep 2020 23:04:34

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:20', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdbebefd-0511-4623-b3d1-fd6a979e4118' User entered 'None (0)'	System	12 Sep 2020 23:04:34
	System	12 Sep 2020 23:04:34

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:22', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdbebefd-0511-4623-b3d1-fd6a979e4118' User entered 'No (N)'	System	12 Sep 2020 23:04:34
	System	12 Sep 2020 23:04:34

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-12T19:04:24', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdbebefd-0511-4623-b3d1-fd6a979e4118' User entered '12 Sep 2020 19:04'	System	12 Sep 2020 23:04:34
	System	12 Sep 2020 23:04:34

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 4'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:44', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4c52e8c7-9614-434c-89f1-bc4e6139cf47'	System	14 Sep 2020 00:51:19
User entered 'No interference with activity (1)'	System	14 Sep 2020 00:51:19

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4c52e8c7-9614-434c-89f1-bc4e6139cf47'	System	14 Sep 2020 00:51:19
User entered 'Some interference with activity (2)'	System	14 Sep 2020 00:51:19

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:52', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4c52e8c7-9614-434c-89f1-bc4e6139cf47'	System	14 Sep 2020 00:51:19
User entered 'Some interference with activity (2)'	System	14 Sep 2020 00:51:19

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4c52e8c7-9614-434c-89f1-bc4e6139cf47'	System	14 Sep 2020 00:51:19
User entered 'Some interference with activity (2)'	System	14 Sep 2020 00:51:19

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:50:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4c52e8c7-9614-434c-89f1-bc4e6139cf47'	System	14 Sep 2020 00:51:19
User entered 'None (0)'	System	14 Sep 2020 00:51:19

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:51:09', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4c52e8c7-9614-434c-89f1-bc4e6139cf47' User entered 'None (0)'	System	14 Sep 2020 00:51:19
	System	14 Sep 2020 00:51:19

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:51:11', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4c52e8c7-9614-434c-89f1-bc4e6139cf47'	System	14 Sep 2020 00:51:19
User entered 'No (N)'	System	14 Sep 2020 00:51:19

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-13T20:51:14', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4c52e8c7-9614-434c-89f1-bc4e6139cf47'	System	14 Sep 2020 00:51:19
User entered '13 Sep 2020 20:51'	System	14 Sep 2020 00:51:19

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 5'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:24', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5072667a-89ce-40ea-b42d-26ddfdc9c7bb' User entered 'None (0)'	System	15 Sep 2020 02:31:52
	System	15 Sep 2020 02:31:52

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:32', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5072667a-89ce-40ea-b42d-26ddfdc9c7bb'	System	15 Sep 2020 02:31:52
User entered 'Some interference with activity (2)'	System	15 Sep 2020 02:31:52

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:36', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5072667a-89ce-40ea-b42d-26ddfdc9c7bb'	System	15 Sep 2020 02:31:52
User entered 'No interference with activity (1)'	System	15 Sep 2020 02:31:52

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:39', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5072667a-89ce-40ea-b42d-26ddfdc9c7bb' User entered 'No interference with activity (1)'	System	15 Sep 2020 02:31:52
	System	15 Sep 2020 02:31:52

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:41', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5072667a-89ce-40ea-b42d-26ddfdc9c7bb' User entered 'None (0)'	System	15 Sep 2020 02:31:52
	System	15 Sep 2020 02:31:52

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:43', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5072667a-89ce-40ea-b42d-26ddfdc9c7bb' User entered 'None (0)'	System	15 Sep 2020 02:31:52
	System	15 Sep 2020 02:31:52

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5072667a-89ce-40ea-b42d-26ddfdc9c7bb' User entered 'No (N)'	System	15 Sep 2020 02:31:52
	System	15 Sep 2020 02:31:52

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-14T22:31:48', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5072667a-89ce-40ea-b42d-26ddfdc9c7bb' User entered '14 Sep 2020 22:31'	System	15 Sep 2020 02:31:52
	System	15 Sep 2020 02:31:52

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 6'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:45', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c164a5cc-764b-450c-a60d-37f1c7940a55'	System	16 Sep 2020 01:36:15
User entered 'No interference with activity (1)'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:48', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c164a5cc-764b-450c-a60d-37f1c7940a55'	System	16 Sep 2020 01:36:15
User entered 'Some interference with activity (2)'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:51', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c164a5cc-764b-450c-a60d-37f1c7940a55'	System	16 Sep 2020 01:36:15
User entered 'Some interference with activity (2)'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c164a5cc-764b-450c-a60d-37f1c7940a55'	System	16 Sep 2020 01:36:15
User entered 'No interference with activity (1)'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:35:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c164a5cc-764b-450c-a60d-37f1c7940a55' User entered 'None (0)'	System	16 Sep 2020 01:36:15
	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:36:01', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c164a5cc-764b-450c-a60d-37f1c7940a55' User entered 'None (0)'	System	16 Sep 2020 01:36:15
	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:36:05', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c164a5cc-764b-450c-a60d-37f1c7940a55'	System	16 Sep 2020 01:36:15
User entered 'Yes (Y)'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-15T21:36:11', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c164a5cc-764b-450c-a60d-37f1c7940a55'	System	16 Sep 2020 01:36:15
User entered '15 Sep 2020 21:36'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	10 Sep 2020 12:48:05
User entered 'Day 7'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 12:48:05

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	16 Sep 2020 01:35:41
User entered 'Day 8'	System	16 Sep 2020 01:35:41

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'afed7fd2-58e2-4709-bbca-d3d419045ee6'	System	18 Sep 2020 11:25:10
User entered 'None (1)'	System	18 Sep 2020 11:25:10

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:07', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'afed7fd2-58e2-4709-bbca-d3d419045ee6' User entered '18 Sep 2020 07:25'	System	18 Sep 2020 11:25:10
	System	18 Sep 2020 11:25:10

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:35:41

US3522109

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:35:41

US3522109

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	16 Sep 2020 01:36:15
User entered 'Day 8'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:01:11

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:13', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7942584a-4118-46aa-916b-9603d4caf4d3' User entered 'None (0)'	System	18 Sep 2020 11:25:20
	System	18 Sep 2020 11:25:20

US3522109

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:15', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7942584a-4118-46aa-916b-9603d4caf4d3'	System	18 Sep 2020 11:25:20
User entered '18 Sep 2020 07:25'	System	18 Sep 2020 11:25:20

US3522109

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	16 Sep 2020 01:36:15
User entered 'Day 8'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:11

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:21', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '46f31b79-48bb-4a0c-b2e0-d29d1dbc1e2e' User entered 'Some interference with activity (2)'	System	18 Sep 2020 11:25:28
	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:24', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '46f31b79-48bb-4a0c-b2e0-d29d1dbc1e2e' User entered '18 Sep 2020 07:25'	System	18 Sep 2020 11:25:28
	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	18 Sep 2020 11:25:28
User entered 'Day 9'	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:11

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-19T00:14:25', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '55fbbbf-bd00d-41b2-b513-149f1e3b7a7b'	System	19 Sep 2020 04:14:41
User entered 'No interference with activity (1)'	System	19 Sep 2020 04:14:41

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-19T00:14:38', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '55fbbbf-bd00d-41b2-b513-149f1e3b7a7b' User entered '19 Sep 2020 00:14'	System	19 Sep 2020 04:14:41
	System	19 Sep 2020 04:14:41

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
Data entry locked.	System	18 Sep 2020 11:25:28
User entered 'Day 10'	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:11

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-19T19:26:25', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '224f2088-5530-40bc-a24c-6863d0ebbf00'	System	19 Sep 2020 23:26:32
User entered 'None (0)'	System	19 Sep 2020 23:26:32

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-19T19:26:27', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '224f2088-5530-40bc-a24c-6863d0ebbf00'	System	19 Sep 2020 23:26:32
User entered '19 Sep 2020 19:26'	System	19 Sep 2020 23:26:32

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:46:19
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	16 Sep 2020 01:36:15
User entered 'Day 8'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9c105d53-013f-4963-8954-7971206d44f1' User entered 'No interference with activity (1)'	System	18 Sep 2020 11:25:38
	System	18 Sep 2020 11:25:38

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:36', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9c105d53-013f-4963-8954-7971206d44f1' User entered '18 Sep 2020 07:25'	System	18 Sep 2020 11:25:38
	System	18 Sep 2020 11:25:38

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	18 Sep 2020 11:25:38
User entered 'Day 9'	System	18 Sep 2020 11:25:38

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:01:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-19T00:14:48', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '827b94e9-712a-4412-b0bc-f778377edbc4' User entered 'None (0)'	System	19 Sep 2020 04:14:55
	System	19 Sep 2020 04:14:55

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-19T00:14:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '827b94e9-712a-4412-b0bc-f778377edbc4' User entered '19 Sep 2020 00:14'	System	19 Sep 2020 04:14:55
	System	19 Sep 2020 04:14:55

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 11:25:38

US3522109

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 11:25:38

US3522109

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	16 Sep 2020 01:36:15
User entered 'Day 8'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ad50e71f-eb39-49b7-83eb-8e9ef6336fae' User entered 'None (0)'	System	18 Sep 2020 11:25:46
	System	18 Sep 2020 11:25:46

US3522109

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:43', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ad50e71f-eb39-49b7-83eb-8e9ef6336fae' User entered '18 Sep 2020 07:25'	System	18 Sep 2020 11:25:46
	System	18 Sep 2020 11:25:46

US3522109

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:36:15

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	16 Sep 2020 01:35:20
User entered 'Day 8'	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:51', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7108b968-c807-4315-a716-8831ab131569'	System	18 Sep 2020 11:26:01
User entered 'No (N)'	System	18 Sep 2020 11:26:01

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-18T07:25:57', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7108b968-c807-4315-a716-8831ab131569'	System	18 Sep 2020 11:26:01
User entered '18 Sep 2020 07:25'	System	18 Sep 2020 11:26:01

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:35:20

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	18 Sep 2020 11:25:28
User entered 'Day 9'	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:11

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 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-19T00:14:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'e8edce56-5192-46d2-a452-dbe64aa82996' User entered 'No (N)'	System	19 Sep 2020 04:15:02
	System	19 Sep 2020 04:15:02

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-09-19T00:14:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'e8edce56-5192-46d2-a452-dbe64aa82996' User entered '19 Sep 2020 00:14'	System	19 Sep 2020 04:15:02
	System	19 Sep 2020 04:15:02

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 11:25:28

US3522109

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:01:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 11:25:28

US3522109

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:54:42

US3522109

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:54:42

US3522109

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:54:42

US3522109

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'ARM SWEELING AT 1ST. DAY 4 DIFFICULTY BREATHING. DAY 5 ED VISIT FOR CHEST PAIN. D-DIMER ELEVATED (POSSIBLE INFLAMMATORY RESPONSE). ALL TESTS NEG. USED ALBUTEROL ONCE. DR. RAMESH SPOKE WITH IN ED.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:02:06
User entered 'ARM SWEELING AT 1ST. DAY 4 DIFFICULTY BREATHING. DAY 5 ER VISIT FOR CHEST PAIN. D-DIMER ELEVATED (POSSIBLE INFLAMMATORY RESPONSE). ALL TESTS NEG. Used ALBUTEROL once. DR. RAMESH SPOKE WITH IN ED.' reason for change: New Information	(b) (4), (b) (6)	17 Sep 2020 19:01:35
User entered 'Arm sweeling at 1st. Day 4 difficulty breathing. Day 5 ER visit for chest pain. D-dimer elevated (possible inflammatory response). All tests neg. Using albuterol. Dr. Ramesh spoke with in ED.'	(b) (4), (b) (6)	17 Sep 2020 18:54:42

US3522109

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:54:48

US3522109

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	17 Sep 2020 18:54:48

US3522109

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	24 Sep 2020 16:38:35

US3522109

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '24 Sep 2020'	Yaman Ahmed (b) (4)	24 Sep 2020 16:38:35

US3522109

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	24 Sep 2020 18:47:25
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	Yaman Ahmed (b) (4)	24 Sep 2020 16:38:35
	(b) (4)	

US3522109

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
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: New Information	(b) (4) Yaman Ahmed (b) (4)	24 Sep 2020 18:47:25
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	24 Sep 2020 16:38:35

US3522109

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	24 Sep 2020 18:47:31

US3522109

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	24 Sep 2020 18:47:31

US3522109

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 14:06:46

US3522109

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered '1 Oct 2020'	Jo-Ann Rammal (b) (4)	01 Oct 2020 14:06:46

US3522109

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Contact Made (CONTACT MADE)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 14:06:46

US3522109

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Pt reports chest heaviness and headache starting 30Sep2020. Pt is taking albuterol inhaler and has not seen PCP. Does not believe symps. related to study drug and does need to speak with study doc.'	Jo-Ann Rammal (b) (4)	01 Oct 2020 14:06:46

US3522109

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:12
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 14:06:54

US3522109

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	01 Oct 2020 14:06:54

US3522109

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:39:43

US3522109

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '9 Oct 2020'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:39:43

US3522109

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[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 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Clinic (Clinic)'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:39:43

US3522109

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'VISIT3'	System	09 Oct 2020 11:39:43

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '9 Oct 2020'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '07:41'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '9 Oct 2020 07:41'	System	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '98.5' F	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Other (Other)'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'temporal'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '80'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'bpm'	System	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '16'	Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'breaths/min'	System	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '122'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '76'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'mmHg'	System	09 Oct 2020 11:42:55

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54

US3522109

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54

US3522109

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	09 Oct 2020 12:06:48

US3522109

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '9 Oct 2020'	(b) (4) Alandra White (b) (4)	09 Oct 2020 12:06:48

US3522109

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:47:16

US3522109

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '9 Oct 2020'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:47:16

US3522109

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered '07:47'	Alandra White (b) (4)	09 Oct 2020 11:47:16

US3522109

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered '9 Oct 2020 07:47'	System	09 Oct 2020 11:47:16

US3522109

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:33:30
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	09 Oct 2020 11:43:02

US3522109

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	09 Oct 2020 11:43:02

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 64'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-16T18:05:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a874e933-ab32-47a0-a031-6c09bdd3ef4b' User entered 'No (N)'	System	16 Oct 2020 22:06:20
	System	16 Oct 2020 22:06:20

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-16T18:05:54', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a874e933-ab32-47a0-a031-6c09bdd3ef4b'	System	16 Oct 2020 22:06:20
User entered 'No (N)'	System	16 Oct 2020 22:06:20

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-16T18:05:59', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a874e933-ab32-47a0-a031-6c09bdd3ef4b' User entered '16 Oct 2020 18:05:59'	System	16 Oct 2020 22:06:20
	System	16 Oct 2020 22:06:20

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 71'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-20T06:56:14', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '793f0b2f-5a26-45b3-b868-5060b8c4611e' User entered 'No (N)'	System	20 Oct 2020 10:56:37
	System	20 Oct 2020 10:56:37

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-20T06:56:26', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '793f0b2f-5a26-45b3-b868-5060b8c4611e' User entered 'No (N)'	System	20 Oct 2020 10:56:37
	System	20 Oct 2020 10:56:37

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-20T06:56:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '793f0b2f-5a26-45b3-b868-5060b8c4611e' User entered '20 Oct 2020 06:56:34'	System	20 Oct 2020 10:56:37
	System	20 Oct 2020 10:56:37

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 78'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-27T06:59:17', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'be50dc5e-501d-4bc0-ac08-5a7d206dd62a' User entered 'No (N)'	System	27 Oct 2020 10:59:35
	System	27 Oct 2020 10:59:35

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-27T06:59:28', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'be50dc5e-501d-4bc0-ac08-5a7d206dd62a'	System	27 Oct 2020 10:59:35
User entered 'No (N)'	System	27 Oct 2020 10:59:35

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-10-27T06:59:33', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'be50dc5e-501d-4bc0-ac08-5a7d206dd62a' User entered '27 Oct 2020 06:59:33'	System	27 Oct 2020 10:59:35
	System	27 Oct 2020 10:59:35

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 92'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-11T16:49:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c9550cf4-d13b-491a-b104-0b3acb4a6750'	System	11 Nov 2020 21:49:54
User entered 'No (N)'	System	11 Nov 2020 21:49:54

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-11T16:49:44', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c9550cf4-d13b-491a-b104-0b3acb4a6750'	System	11 Nov 2020 21:49:54
User entered 'No (N)'	System	11 Nov 2020 21:49:54

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-11T16:49:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c9550cf4-d13b-491a-b104-0b3acb4a6750' User entered '11 Nov 2020 16:49:49'	System	11 Nov 2020 21:49:54
	System	11 Nov 2020 21:49:54

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered 'Day 99'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-17T06:40:02', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '035df981-3559-4e5c-9b9e-787e4b1bf62f' User entered 'Yes (Y)'	System	17 Nov 2020 11:40:39
	System	17 Nov 2020 11:40:39

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-17T06:40:06', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '035df981-3559-4e5c-9b9e-787e4b1bf62f' User entered 'No (N)'	System	17 Nov 2020 11:40:39
	System	17 Nov 2020 11:40:39

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-17T06:40:11', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '035df981-3559-4e5c-9b9e-787e4b1bf62f' User entered 'No (N)'	System	17 Nov 2020 11:40:39
	System	17 Nov 2020 11:40:39

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-17T06:40:15', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '035df981-3559-4e5c-9b9e-787e4b1bf62f' User entered 'Yes (Y)'	System	17 Nov 2020 11:40:39
	System	17 Nov 2020 11:40:39

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-17T06:40:21', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '035df981-3559-4e5c-9b9e-787e4b1bf62f'	System	17 Nov 2020 11:40:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 11:40:39

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-17T06:40:28', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '035df981-3559-4e5c-9b9e-787e4b1bf62f' User entered '17 Nov 2020 06:40:28'	System	17 Nov 2020 11:40:39
	System	17 Nov 2020 11:40:39

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 12:57:40

US3522109

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:36:35
Data entry locked.	System	13 Aug 2020 12:57:40
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 12:57:40

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-24T17:38:08', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '77ac8b4c-0f30-454b-bc28-ffc0bdbfa860' User entered 'Yes (Y)'	System	24 Nov 2020 22:38:56

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-24T17:38:13', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '77ac8b4c-0f30-454b-bc28-ffc0bdbfa860' User entered 'No (N)'	System	24 Nov 2020 22:38:56

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-24T17:38:27', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '77ac8b4c-0f30-454b-bc28-ffc0bdbfa860' User entered 'No (N)'	System	24 Nov 2020 22:38:56

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-24T17:38:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '77ac8b4c-0f30-454b-bc28-ffc0bdbfa860' User entered 'Yes (Y)'	System	24 Nov 2020 22:38:56

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-24T17:38:41', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '77ac8b4c-0f30-454b-bc28-ffc0bdbfa860'	System	24 Nov 2020 22:38:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 22:38:56

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-24T17:38:47', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '77ac8b4c-0f30-454b-bc28-ffc0bdbfa860' User entered '24 Nov 2020 17:38:47'	System	24 Nov 2020 22:38:56
	System	24 Nov 2020 22:38:56

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:41:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered 'Yes (Y)'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:41:50', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered 'No (N)'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:41:57', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered 'Yes (Y)'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '1'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '1'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '1'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53
	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '1'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53
	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53
	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53
	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53
	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53
	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '0'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:28', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9'	System	28 Nov 2020 13:42:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:32', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered 'Yes (Y)'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:37', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9'	System	28 Nov 2020 13:42:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-11-28T08:42:43', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'a023f0e2-7b9c-4601-8c8b-85c09c04b2e9' User entered '28 Nov 2020 08:42:43'	System	28 Nov 2020 13:42:53
	System	28 Nov 2020 13:42:53

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-05T00:01:48', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'aa130532-c48d-4d3d-9d76-62b88c09dbc4' User entered 'No (N)'	System	05 Dec 2020 05:02:15

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-05T00:01:53', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'aa130532-c48d-4d3d-9d76-62b88c09dbc4'	System	05 Dec 2020 05:02:15
User entered 'No (N)'	System	05 Dec 2020 05:02:15

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-05T00:01:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'aa130532-c48d-4d3d-9d76-62b88c09dbc4'	System	05 Dec 2020 05:02:15
User entered '05 Dec 2020 00:01:58'	System	05 Dec 2020 05:02:15

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-12T14:04:22', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b4787ebe-72be-4574-8def-f74ca1843cf5' User entered 'Yes (Y)'	System	12 Dec 2020 19:04:44
	System	12 Dec 2020 19:04:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-12T14:04:27', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b4787ebe-72be-4574-8def-f74ca1843cf5' User entered 'No (N)'	System	12 Dec 2020 19:04:44
	System	12 Dec 2020 19:04:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-12T14:04:31', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b4787ebe-72be-4574-8def-f74ca1843cf5' User entered 'No (N)'	System	12 Dec 2020 19:04:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-12T14:04:36', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b4787ebe-72be-4574-8def-f74ca1843cf5' User entered 'No (N)'	System	12 Dec 2020 19:04:44
	System	12 Dec 2020 19:04:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-12T14:04:41', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'b4787ebe-72be-4574-8def-f74ca1843cf5' User entered '12 Dec 2020 14:04:41'	System	12 Dec 2020 19:04:44
	System	12 Dec 2020 19:04:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-19T01:35:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ae14ecce-4a35-4e97-b682-a014da0ba458'	System	19 Dec 2020 06:36:07
User entered 'No (N)'	System	19 Dec 2020 06:36:07

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-19T01:35:58', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ae14ecce-4a35-4e97-b682-a014da0ba458'	System	19 Dec 2020 06:36:07
User entered 'No (N)'	System	19 Dec 2020 06:36:07

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-19T01:36:02', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ae14ecce-4a35-4e97-b682-a014da0ba458' User entered '19 Dec 2020 01:36:02'	System	19 Dec 2020 06:36:07
	System	19 Dec 2020 06:36:07

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-28T00:53:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '534f3569-bc8f-4ce9-a024-aeffa15c4ef7' User entered 'No (N)'	System	28 Dec 2020 08:53:58
	System	28 Dec 2020 08:53:58

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-28T00:53:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '534f3569-bc8f-4ce9-a024-ae9a15c4ef7'	System	28 Dec 2020 08:53:58
User entered 'No (N)'	System	28 Dec 2020 08:53:58

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2020-12-28T00:53:54', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '534f3569-bc8f-4ce9-a024-ae15c4ef7' User entered '28 Dec 2020 00:53:54'	System	28 Dec 2020 08:53:58

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-06T13:17:12', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'e259a1c2-abf7-4a91-9e92-acc9349e785a' User entered 'No (N)'	System	06 Jan 2021 18:17:21
	System	06 Jan 2021 18:17:21

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-06T13:17:15', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'e259a1c2-abf7-4a91-9e92-acc9349e785a' User entered 'No (N)'	System	06 Jan 2021 18:17:21

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-06T13:17:18', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'e259a1c2-abf7-4a91-9e92-acc9349e785a' User entered '06 Jan 2021 13:17:18'	System	06 Jan 2021 18:17:21
	System	06 Jan 2021 18:17:21

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-09T00:01:55', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2821aca3-8590-4a40-87ca-0a562835ac92'	System	09 Jan 2021 05:02:27
User entered 'No (N)'	System	09 Jan 2021 05:02:27

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-09T00:02:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2821aca3-8590-4a40-87ca-0a562835ac92'	System	09 Jan 2021 05:02:27
User entered 'No (N)'	System	09 Jan 2021 05:02:27

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-09T00:02:04', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '2821aca3-8590-4a40-87ca-0a562835ac92' User entered '09 Jan 2021 00:02:04'	System	09 Jan 2021 05:02:27
	System	09 Jan 2021 05:02:27

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-16T00:19:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '89a8f3bf-f2d6-4e4c-a5dd-da29d3952e04'	System	16 Jan 2021 05:19:57
User entered 'No (N)'	System	16 Jan 2021 05:19:57

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-16T00:19:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '89a8f3bf-f2d6-4e4c-a5dd-da29d3952e04'	System	16 Jan 2021 05:19:57
User entered 'No (N)'	System	16 Jan 2021 05:19:57

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-16T00:19:53', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '89a8f3bf-f2d6-4e4c-a5dd-da29d3952e04' User entered '16 Jan 2021 00:19:53'	System	16 Jan 2021 05:19:57
	System	16 Jan 2021 05:19:57

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-24T20:06:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '04d0aedd-db71-4a52-b379-6720ce155d5c' User entered 'No (N)'	System	25 Jan 2021 01:06:55
	System	25 Jan 2021 01:06:55

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-24T20:06:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '04d0aedd-db71-4a52-b379-6720ce155d5c' User entered 'No (N)'	System	25 Jan 2021 01:06:55

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-24T20:06:53', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '04d0aedd-db71-4a52-b379-6720ce155d5c' User entered '24 Jan 2021 20:06:53'	System	25 Jan 2021 01:06:55

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-30T01:09:42', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '51ebd93e-53d2-4543-9dc1-7c72ac917272'	System	30 Jan 2021 06:09:54
User entered 'No (N)'	System	30 Jan 2021 06:09:54

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-30T01:09:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '51ebd93e-53d2-4543-9dc1-7c72ac917272'	System	30 Jan 2021 06:09:54
User entered 'No (N)'	System	30 Jan 2021 06:09:54

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-01-30T01:09:52', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '51ebd93e-53d2-4543-9dc1-7c72ac917272' User entered '30 Jan 2021 01:09:52'	System	30 Jan 2021 06:09:54
	System	30 Jan 2021 06:09:54

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-06T00:01:29', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9920451c-ba45-48d2-826a-d7f8e09b88b0' User entered 'No (N)'	System	06 Feb 2021 05:02:20
	System	06 Feb 2021 05:02:20

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-06T00:01:34', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9920451c-ba45-48d2-826a-d7f8e09b88b0' User entered 'No (N)'	System	06 Feb 2021 05:02:20
	System	06 Feb 2021 05:02:20

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-06T00:01:41', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '9920451c-ba45-48d2-826a-d7f8e09b88b0' User entered '06 Feb 2021 00:01:41'	System	06 Feb 2021 05:02:20
	System	06 Feb 2021 05:02:20

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-13T00:17:43', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4495c31b-bc8e-4b9f-b443-63aa26e6bb97' User entered 'No (N)'	System	13 Feb 2021 05:18:10

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-13T00:17:46', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4495c31b-bc8e-4b9f-b443-63aa26e6bb97' User entered 'No (N)'	System	13 Feb 2021 05:18:10

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-13T00:17:49', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '4495c31b-bc8e-4b9f-b443-63aa26e6bb97' User entered '13 Feb 2021 00:17:49'	System	13 Feb 2021 05:18:10
	System	13 Feb 2021 05:18:10

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-20T00:12:37', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdf28f42-4b18-46e8-93e1-c43ee53c75bf' User entered 'No (N)'	System	20 Feb 2021 05:12:49
	System	20 Feb 2021 05:12:49

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-20T00:12:40', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdf28f42-4b18-46e8-93e1-c43ee53c75bf' User entered 'No (N)'	System	20 Feb 2021 05:12:49

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-20T00:12:44', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'cdf28f42-4b18-46e8-93e1-c43ee53c75bf' User entered '20 Feb 2021 00:12:44'	System	20 Feb 2021 05:12:49

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-27T06:03:31-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ecfae2a3-ad46-4e74-b513-275bbb925e0d' User entered 'No (N)'	System	27 Feb 2021 11:03:41

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-27T06:03:34-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ecfae2a3-ad46-4e74-b513-275bbb925e0d' User entered 'No (N)'	System	27 Feb 2021 11:03:41

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-02-27T06:03:37-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'ecfae2a3-ad46-4e74-b513-275bbb925e0d' User entered '27 Feb 2021 11:03:37'	System	27 Feb 2021 11:03:41
	System	27 Feb 2021 11:03:41

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-10T14:35:18-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '925b9b52-d1bc-4bd8-bb33-05f56e4c1f20' User entered 'No (N)'	System	10 Mar 2021 19:35:38
	System	10 Mar 2021 19:35:38

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-10T14:35:28-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '925b9b52-d1bc-4bd8-bb33-05f56e4c1f20'	System	10 Mar 2021 19:35:38
User entered 'No (N)'	System	10 Mar 2021 19:35:38

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-10T14:35:34-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '925b9b52-d1bc-4bd8-bb33-05f56e4c1f20' User entered '10 Mar 2021 14:35:34'	System	10 Mar 2021 19:35:38
	System	10 Mar 2021 19:35:38

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-13T02:14:53-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7f912ac0-e6bc-495d-9fa3-97c38870939e' User entered 'No (N)'	System	20 Mar 2021 04:04:31

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-13T02:14:58-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7f912ac0-e6bc-495d-9fa3-97c38870939e' User entered 'No (N)'	System	20 Mar 2021 04:04:31

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-13T02:15:05-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '7f912ac0-e6bc-495d-9fa3-97c38870939e'	System	20 Mar 2021 04:04:31
User entered '13 Mar 2021 02:15:05'	System	20 Mar 2021 04:04:31

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-20T00:02:20-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '6b2afdb7-6e61-40e7-8e09-9d5a73f11026'	System	20 Mar 2021 04:04:32
User entered 'No (N)'	System	20 Mar 2021 04:04:32

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-20T00:02:22-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '6b2afdb7-6e61-40e7-8e09-9d5a73f11026'	System	20 Mar 2021 04:04:32
User entered 'No (N)'	System	20 Mar 2021 04:04:32

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-20T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '6b2afdb7-6e61-40e7-8e09-9d5a73f11026'	System	20 Mar 2021 04:04:32
User entered '20 Mar 2021 00:02:26'	System	20 Mar 2021 04:04:32

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-27T00:02:47-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '8a959922-467a-4f94-a95d-0bf7cac5074a'	System	27 Mar 2021 04:08:29
User entered 'No (N)'	System	27 Mar 2021 04:08:29

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-27T00:02:50-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '8a959922-467a-4f94-a95d-0bf7cac5074a'	System	27 Mar 2021 04:08:29
User entered 'No (N)'	System	27 Mar 2021 04:08:29

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-27T00:02:53-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '8a959922-467a-4f94-a95d-0bf7cac5074a' User entered '27 Mar 2021 00:02:53'	System	27 Mar 2021 04:08:29
	System	27 Mar 2021 04:08:29

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-03T00:02:32-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'dcc49bb6-7a1e-4efb-a6c3-ab0d3fd95e3b'	System	03 Apr 2021 04:03:55
User entered 'No (N)'	System	03 Apr 2021 04:03:55

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-03T00:02:39-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'dcc49bb6-7a1e-4efb-a6c3-ab0d3fd95e3b'	System	03 Apr 2021 04:03:55
User entered 'No (N)'	System	03 Apr 2021 04:03:55

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-03T00:02:42-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'dcc49bb6-7a1e-4efb-a6c3-ab0d3fd95e3b'	System	03 Apr 2021 04:03:55
User entered '03 Apr 2021 00:02:42'	System	03 Apr 2021 04:03:55

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-10T00:02:29-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c466d1ad-ffb4-4427-a145-156b43c22edb' User entered 'No (N)'	System	10 Apr 2021 04:05:48

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-10T00:02:39-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c466d1ad-ffb4-4427-a145-156b43c22edb' User entered 'No (N)'	System	10 Apr 2021 04:05:48

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-10T00:02:44-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c466d1ad-ffb4-4427-a145-156b43c22edb' User entered '10 Apr 2021 00:02:44'	System	10 Apr 2021 04:05:48
	System	10 Apr 2021 04:05:48

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-17T01:46:20-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5cbccc18-bda0-453e-9a92-f7936ebaf6c3'	System	17 Apr 2021 05:46:31
User entered 'No (N)'	System	17 Apr 2021 05:46:31

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-17T01:46:23-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5cbccc18-bda0-453e-9a92-f7936ebaf6c3'	System	17 Apr 2021 05:46:31
User entered 'No (N)'	System	17 Apr 2021 05:46:31

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-17T01:46:27-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: '5cbccc18-bda0-453e-9a92-f7936ebaf6c3'	System	17 Apr 2021 05:46:31
User entered '17 Apr 2021 01:46:27'	System	17 Apr 2021 05:46:31

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-24T01:03:52-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c188e3ba-f534-4a5d-a2ef-a34d23c0adde' User entered 'No (N)'	System	24 Apr 2021 05:04:08

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

Have you been exposed to someone with 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 (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-24T01:03:54-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c188e3ba-f534-4a5d-a2ef-a34d23c0adde' User entered 'No (N)'	System	24 Apr 2021 05:04:08

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-04-24T01:04:02-04:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'c188e3ba-f534-4a5d-a2ef-a34d23c0adde'	System	24 Apr 2021 05:04:08
User entered '24 Apr 2021 01:04:02'	System	24 Apr 2021 05:04:08

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 05:39:44

US3522109

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:01:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:39:44
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 05:39:44

US3522109

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:01:11

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 19:55:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-02T22:39:36-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fce430f0-496a-493e-aa1c-940abe6259d1'	System	10 Mar 2021 19:35:13
User entered 'No (N)'	System	10 Mar 2021 19:35:13

US3522109

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:01:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:55:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96E09B45-D9B7-492F-AD9F-4D474F257D6A)', Time: '2021-03-02T22:39:49-05:00', User OID: 'PatientReportedOutcome (US3522109)', ODM File OID: 'fce430f0-496a-493e-aa1c-940abe6259d1' User entered '02 Mar 2021 22:39:49'	System	10 Mar 2021 19:35:13
	System	10 Mar 2021 19:35:13

US3522109

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:54:49

US3522109

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:54:49

US3522109

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:54:49

US3522109

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
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)	05 Nov 2020 15:54:49

US3522109

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:54:53

US3522109

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:29:54
User entered 'I'	System	05 Nov 2020 15:54:53

US3522109

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	09 Dec 2020 22:01:13

US3522109

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '10 Dec 2020' reason for change: New Information	(b) (4)	
	Yaman Ahmed (b) (4)	10 Dec 2020 16:12:48
User entered '9 Dec 2020'	(b) (4)	
	Yaman Ahmed (b) (4)	09 Dec 2020 22:01:13
	(b) (4)	

US3522109

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	10 Dec 2020 16:12:48
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	Yaman Ahmed (b) (4)	09 Dec 2020 22:01:13
	(b) (4)	

US3522109

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Review specified comment, AES REPORTED ON 28 NOV 2020 (SOB, COUGH, AND BODY ACHES). Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 09:09:26
Query 'Per DM CLR: Review specified comment, AES REPORTED ON 28 NOV 2020 (SOB, COUGH, AND BODY ACHES). Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate. ' answered with 'Please clarify and Read AEs and narratives. They already are there.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	11 Feb 2021 21:08:20
User opened query 'Per DM CLR: Review specified comment, AES REPORTED ON 28 NOV 2020 (SOB, COUGH, AND BODY ACHES). Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:28:18
User entered 'AES REPORTED ON 28 NOV 2020 (SOB, COUGH, FATIGUE, AND BODY ACHES) ARE MUCH IMPROVED BUT NOT COMPLETELY GONE. CONTINUES TO RECOVER FROM RECENT ILLNESS (26 NOV 2020 TO 01 DEC 2020 HOSPITALIZATION)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 16:13:44
User entered 'AEs reported on 28 Nov 2020 (SOB, cough, fatigue, and body aches) are much improved but not completely gone. Continues to recover from recent illness (26 Nov 2020 to 01 Dec 2020 hospitalization for pericardial effusion) and though has improved enough to return to work on 07 Dec 2020, she's not yet at complete baseline.' (non-conformant).	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 16:12:48
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	09 Dec 2020 22:01:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3522109

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	10 Dec 2020 16:13:52

US3522109

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'I'	System	10 Dec 2020 16:13:52

US3522109

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:54:29

US3522109

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:54:29

US3522109

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:54:29

US3522109

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'call attempted; vm left'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 20:54:29

US3522109

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:39:44

US3522109

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'I'	System	06 Feb 2021 15:39:44

US3522109

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:39:57

US3522109

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '6 Feb 2021'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:39:57

US3522109

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:39:57

US3522109

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Still taking prednisone, tapering down slowly, currently taking 5mg. Following up with rheumatology on Tuesday to further look into possible causes for inflammation.'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:39:57

US3522109

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	06 Feb 2021 15:40:01

US3522109

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'I'	System	06 Feb 2021 15:40:01

US3522109

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:46:12

US3522109

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:46:12

US3522109

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[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 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:46:12

US3522109

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'VISIT4'	System	09 Mar 2021 13:46:12

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered '09 Mar 2021'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered '08:05'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered '09 Mar 2021 08:05'	System	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered '97.9' F	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered 'Other (Other)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered 'temporal'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered '64'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'bpm'	System	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered '14'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'breaths/min'	System	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered '140'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'mmHg'	System	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	01 Apr 2021 18:55:29
User entered '83'	(b) (4) Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'mmHg'	System	30 Mar 2021 19:22:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28

US3522109

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:01:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28

US3522109

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:46:22

US3522109

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:01:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:46:22

US3522109

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:46:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	09 Mar 2021 13:46:47
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	09 Mar 2021 13:46:47
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:46:47
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 13:46:35
User entered '09 Feb 2021'	(b) (4), (b) (6)	09 Mar 2021 13:46:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '08:08'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:46:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered '09 Mar 2021 08:08'	System	09 Mar 2021 13:46:47
User entered '09 Feb 2021 08:08'	System	09 Mar 2021 13:46:35

US3522109

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:46:39

US3522109

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:45:28
User entered 'I'	System	09 Mar 2021 13:46:39

US3522109

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	08 Apr 2021 16:33:44
	(b) (4)	

US3522109

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
User entered '8 Apr 2021'	Yaman Ahmed (b) (4)	08 Apr 2021 16:33:44
	(b) (4)	

US3522109

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	08 Apr 2021 16:33:44

US3522109

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:01:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'Has been feeling very well and will be going for cardiology follow-up on 13 Apr 2021 when she hopes to be taken off the colchicine. Otherwise, no other changes in health, no covid-19 exposures'	(b) (4) Yaman Ahmed (b) (4)	08 Apr 2021 16:33:44

US3522109

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	08 Apr 2021 16:33:51
	(b) (4)	

US3522109

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:01:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 16:33:51

US3522109

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:11

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:41:14

US3522109

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '10:30'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:41:14

US3522109

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:11

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:03
User entered '25 Nov 2020 10:30'	System	25 Nov 2020 15:41:14

US3522109

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:11

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:41:14

US3522109

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:01:11

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Jan 2021 15:29:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:41:14

US3522109

Folder: Covid-19 Assessment 25 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:01:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:17:10
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Mar 2021 18:35:33

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:33:41

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:33:41

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[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 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:33:41

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:01:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered 'UNBLND_DECIDE'	System	11 Feb 2021 13:33:41

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '11 Feb 2021' reason for change: Data Entry Error	Sharon Mathys (b) (4)	11 Feb 2021 14:02:03
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[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 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:47:32

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4)	11 Feb 2021 14:02:03
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	11 Feb 2021 14:02:03
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	11 Feb 2021 13:52:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
User entered 'AMENDMENT 5 (AMENDMENT 5)'	(b) (4) System	10 Mar 2021 16:55:28
WR# 5295537		
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:47:32

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:18:29
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Unblinded due to safety concern possibly prior to amendment 5. See SAEs' (Site from System).	Sharon Mathys (b) (4) (b) (4)	11 Feb 2021 14:02:32
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	11 Feb 2021 14:02:03
User entered '02 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	11 Feb 2021 14:02:03
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:01:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered empty.	System	11 Feb 2021 13:52:56

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 13:33:58

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Feb 2021 13:34:02
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	11 Feb 2021 13:34:02
User entered '11 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 13:34:02
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Feb 2021 13:33:58
User entered '11 Jan 2021'	(b) (4), (b) (6)	11 Feb 2021 13:33:58

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '07:51'	(b) (4), (b) (6)	11 Feb 2021 13:33:58

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:01:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '11 Feb 2021 07:51'	System	11 Feb 2021 13:34:02
User entered '11 Jan 2021 07:51'	System	11 Feb 2021 13:33:58

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:34:17

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 13:34:17

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '07:52'	(b) (4), (b) (6)	11 Feb 2021 13:34:17

US3522109

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:01:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:39:32
User entered '11 Feb 2021 07:52'	System	11 Feb 2021 13:34:17

US3522109

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:01:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:08

User closed query 'Per CDM RQ: Response noted, however note that per Diary dose 2, Muscle aches all over was started on 13Sept 2020. Please reconcile and update start date of AE recorded accordingly or else clarify.	(b) (4), (b) (6)	27 Apr 2021 05:08:50
---	------------------	----------------------

' (Site from DM).

Query 'Per CDM RQ: Response noted, however note that per Diary dose 2, Muscle aches all over was started on 13Sept 2020. Please reconcile and update start date of AE recorded accordingly or else clarify.	Sharon Mathys (b) (4) (b) (4)	26 Apr 2021 12:07:13
---	----------------------------------	----------------------

' answered with 'To have accurate recording, it was lumped by grade as we could not get clarity from the PPD team on request how to deal with grade changes with timelines of SAR. Since Day 7 was not recorded (and no mention of what grade it was is present in source for safety calls) and Day 6 was Grade 2 with Day 8 as Grade 1, it was decided the most accurate recording would put the start time at Day 8 as the other days are already present.' (Site from DM).

User opened query 'Per CDM RQ: Response noted, however note that per Diary dose 2, Muscle aches all over was started on 13Sept 2020. Please reconcile and update start date of AE recorded accordingly or else clarify.	(b) (4), (b) (6)	23 Apr 2021 02:34:02
---	------------------	----------------------

' (Site from DM).

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:01:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, MUSCLE ACHES ALL OVER lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 02:34:02
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, MUSCLE ACHES ALL OVER lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'added' (Site from DM).	Sharon Mathys (b) (4)	21 Apr 2021 16:52:41
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, MUSCLE ACHES ALL OVER lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 18:45:13
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	16 Sep 2020 12:54:04

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:36:20
Query 'Per MM: Please update to reflect the etiology, if known. ' answered with 'Please clarify what terminology would be appropriate in this case as scans did not show anything at the time and we have had issues answering coding queries to dm satisfaction' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	18 Dec 2020 17:38:34
User opened query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 06:39:50
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 07:05:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 07:05:19
Data point term sent to Coder	System	19 Nov 2020 12:48:55
User closed query 'CDM Coding: As per the query response kindly update the term as 'PAIN IN UPPER RIGHT CHEST NOS'.' (Site from System).	System	19 Nov 2020 12:48:22
Query 'CDM Coding: As per the query response kindly update the term as 'PAIN IN UPPER RIGHT CHEST NOS'.' answered with 'Updated per query' (Site from System).	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 12:48:22
User entered 'PAIN IN UPPER RIGHT CHEST NOS' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 12:48:11
User opened query 'CDM Coding: As per the query response kindly update the term as 'PAIN IN UPPER RIGHT CHEST NOS'.' (Site from System).	Coder Import (b) (4) (b) (4)	19 Nov 2020 06:39:54
Data point term sent to Coder	System	17 Nov 2020 18:05:18
User closed query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain to enable coding' (Site from System).	System	17 Nov 2020 18:04:48

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
Query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain to enable coding' answered with 'Cannot definitively state. Discharge did not have a cause for the chest pain.' (Site from System).	Sharon Mathys (b) (4)	17 Nov 2020 18:04:48
User opened query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain to enable coding' (Site from System).	Coder Import (b) (4)	12 Nov 2020 23:54:38
Data point term sent to Coder	System	22 Oct 2020 16:40:12
User closed query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' (Site from System).	System	22 Oct 2020 16:39:57
Query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' answered with 'pt seen in ED, all studies negative for cardiac/respiratory process' (Site from System).	Alandra White (b) (4)	22 Oct 2020 16:39:57
User opened query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' (Site from System).	Coder Import (b) (4)	22 Oct 2020 08:41:23
Data point term sent to Coder	System	21 Oct 2020 18:54:55
User closed query 'CDM Coding: Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Chest pain - cardiac, Musculoskeletal chest pain, Chest pain – non cardiac etc)' (Site from System).	System	21 Oct 2020 18:54:48
Query 'CDM Coding: Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Chest pain - cardiac, Musculoskeletal chest pain, Chest pain – non cardiac etc)' answered with 'was listed as chest pain, unspecified type in medical records.' (Site from System).	Sharon Mathys (b) (4)	21 Oct 2020 18:54:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: Please clarify this clinical event with more details and amend /update the term accordingly in the diagnosis field to enable coding. (e.g, Chest pain - cardiac, Musculoskeletal chest pain, Chest pain – non cardiac etc)' (Site from System).	Coder Import (b) (4)	08 Oct 2020 05:30:15
Data point term sent to Coder	System	16 Sep 2020 13:08:03
User entered 'Pain in upper right chest'	Sharon Mathys (b) (4)	16 Sep 2020 13:07:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '13 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:31:41
User entered '14 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:12:51
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '15 Sep 2020' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:12:51
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 05:20:50
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Confirmed. Grade 4 because she went to the ER, but had tests done and was discharged feeling better. Not treated as inpatient. Unsure on cause as of yet, test results taken at ER visit not fully back.' (Site from System).	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:12:35
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	16 Sep 2020 13:09:44
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Sep 2020 13:09:44
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:09:44
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Sep 2020 13:07:49
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 13:09:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 13:09:44
User entered 'Related (RELATED)' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:09:44
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 13:07:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, patient took Aspirin and Naproxen. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 14:21:21
Query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, patient took Aspirin and Naproxen. Please review and add a Con Medication as appropriate or update action taken.' answered with 'They also take that normally so it doubles up medications. No good way to document.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 17:51:11
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is still NO Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, patient took Aspirin and Naproxen. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:50:38
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 05:52:49
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'medications for hospitalization added' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 19:22:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User entered 'I'	(b) (4), (b) (6) (b) (4)	12 Dec 2020 05:29:57
	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:48:11
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'It is still a procedure. Clarify if only some procedures are necessary here' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:18:28
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:50:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:31:48
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:12:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'WENT TO THE ED COMPLAINING OF CHEST PAIN FOR THE PAST 2 DAYS. PAIN EXACERBATED WITH LEANING FORWARD AND DEEP INSPIRATION. TOOK ASPIRIN, NAPROXEN LAST NIGHT. CHEST PAIN, UNSPECIFIED TYPE: DIAGNOSIS MANAGEMENT COMMENTS: PT PRESENTS WITH SOME DIZZINESS AND RIGHT SIDED CHEST PAIN. PT DID RECEIVE SECOND DOSE OF THE COVID VACCINE 5 DAYS AGO. BENIGN EXAM AND NORMAL VITALS. LAB WORK IS SIGNIFICANT FOR ELEVATED D-DIMER. CT CHEST IS NEGATIVE FOR PE OR ANY OTHER ACUTE PROCESS. PT WILL BE DISCHARGED TO FOLLOW UP WITH PCP. PATIENT UNDERSTANDS AND AGREES WITH TREATMENT PLAN.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:35:38
User entered 'Went to the ED complaining of Chest pain for the past 2 days. Pain exacerbated with leaning forward and deep inspiration. Took Aspirin, Naproxen last night. Chest pain, unspecified type: Diagnosis management comments: Pt presents with some dizziness and right sided chest pain. Pt did receive second dose of the COVID vaccine 5 days ago. benign exam and normal vitals. Lab work is significant for elevated d-dimer. CT chest is negative for PE or any other acute process. Pt will be discharged to follow up with PCP. Patient understands and agrees with treatment plan.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:31:41
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Sep 2020 13:09:44
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	16 Sep 2020 13:09:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Sep 2020 13:07:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Sep 2020 13:09:44
User entered '1'	System	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 13:07:49

US3522109

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Heaviness is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. 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)	25 Jan 2021 05:50:17
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Heaviness is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Likely related to SAEs but cannot confirm as there is no direct test point towards it. Give us exactly terminology you would like or do not requery' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 17:53:30
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Heaviness is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. 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)	14 Jan 2021 00:52:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest heaviness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:00:58
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 18:00:58
Data point term sent to Coder	System	02 Dec 2020 13:46:50
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	02 Dec 2020 13:45:59

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'CHEST HEAVINESS Intermittent' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 13:45:59
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST HEAVINESS is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. 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)	26 Oct 2020 04:20:30
User closed query '1) Per MM: Please update to reflect the etiology, if known. 2) Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:46:00
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST HEAVINESS is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'unknown diagnosis- pt seen in ED 9/15/2020 with elevated d-dimer but negative tests/exam for cardiac/respiratory process. Follow up with primary care physician found pt to "be in good health" per pt report, spoke with study physician (Dr. Ramesh) 9/16/2020 and no covid testing was deemed to be indicated at that time ' (Site from DM).	Alandra White (b) (4) (b) (4)	22 Oct 2020 16:46:49

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Query '1) Per MM: Please update to reflect the etiology, if known. 2) Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'not a covid-19 symptom' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	21 Oct 2020 18:42:53
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if CHEST HEAVINESS is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. 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)	21 Oct 2020 06:33:15
User opened query '1) Per MM: Please update to reflect the etiology, if known. 2) Per MM: Please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:39:44
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest heaviness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:52:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:52:22
Data point term sent to Coder	System	01 Oct 2020 13:50:55
User entered 'Chest heaviness'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '30 Sep 2020'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
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 Oct 2020 13:52:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 13:52:02
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 13:52:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 13:51:27
User entered 'UK:UK' (non-conformant).	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:51:27
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 Oct 2020 13:50:09
User entered '08:00'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:52:02
User entered '30 Sep 2020 UK:UK' (non-conformant).	System	01 Oct 2020 13:51:27
User entered '30 Sep 2020 08:00'	System	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:05:55
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 04:51:04
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	02 Dec 2020 13:46:05
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 22:40:30
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '03 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	07 Dec 2020 15:05:55
User entered empty.	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

US3522109

Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

US3522109

Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Dec 2020 13:45:59
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:51:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:51:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:51:27
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:50:09
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:51:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:51:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:51:27
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:50:09
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:51:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:51:27
User entered 'None (NONE)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:51:27
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:50:09
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:55:59
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	01 Oct 2020 13:52:02
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	01 Oct 2020 13:51:27
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	01 Oct 2020 13:51:27
User entered '1' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:51:27
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	01 Oct 2020 13:50:09
User entered '0'	System	01 Oct 2020 13:50:09
	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:50:09
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR - RQ: Site's response noted. However, CM (ALBUTEROL and NAPROXEN) indication does not include this AE in the CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 14:27:50
Query 'Per DM CLR - RQ: Site's response noted. However, CM (ALBUTEROL and NAPROXEN) indication does not include this AE in the CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify.' answered with 'Overlaps with normally taken pain medication, no good way to document' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 17:53:50
User opened query 'Per DM CLR - RQ: Site's response noted. However, CM (ALBUTEROL and NAPROXEN) indication does not include this AE in the CM eCRF. Please review and verify if the same medication was given for this AE. If yes, add this AE to the CM indication so there will be an appropriate match. Update eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:52:10
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Per DM CLR: RQ: Response noted, however, please update the CM's Indication field to include this AE term as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:44:14
Query 'Per DM CLR: RQ: Response noted, however, please update the CM's Indication field to include this AE term as appropriate. Otherwise, clarify.' answered with 'CM of albuterol used for chest heaviness that is result of asthma listed in medical history ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:50:18

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: RQ: Response noted, however, please update the CM's Indication field to include this AE term as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:00:55
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)	26 Oct 2020 04:33:14
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 'pt used albuterol inhaler that she uses for asthma ' (Site from DM).	Alandra White (b) (4)	22 Oct 2020 16:48:08
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)	21 Oct 2020 06:33:28
User entered '1' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:55:59
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	01 Oct 2020 13:52:02
User entered '1' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:51:27
User entered '0'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:05:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:55:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 13:52:02
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:51:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:51:27
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:51:27
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:50:09
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Form: Adverse Events (2)

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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)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Described to staff as chest heaviness, also as upper right chest pain returned after having been gone after hospital visit on 15sep2020. Started again intermittantly on 30sep2020 and was until 03oct2020. During PCP visit on 05oct2020 had no issues. Was asymptomatic at Visit 3 on 09 Oct 2020.Used albuterol inhaler to try to help and naproxen that also is taken for asthma and knee pain respectively. Pain appeared to go away over time' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:05:55
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 13:50:09

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE HEADACHES . If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 05:51:07
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE HEADACHES . If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'likely related, not a worsening as the headaches are intermittent. Please clarify if we should even report these events.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 17:54:33
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of MIGRAINE HEADACHES . If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:52:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query ' Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:48:56

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Query ' Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Pt did not feel need to report headache symptoms experienced 30Sep2020 due to symptoms mirroring to a lesser extent AE that had previously happened on 14Sep2020. Pt is physician and had no known exposure; does not believe to be r/t study drug and did not feel need to speak with study physician ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:01:31
User opened query ' Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 03:22:09
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 14:02:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 14:02:56
Data point term sent to Coder	System	01 Oct 2020 14:02:17
User entered 'Headache'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '30 Sep 2020'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 12:34:54
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'Updated' (Site from DM).	Sharon Mathys (b) (4)	07 Dec 2020 15:09:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 15:09:00
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 22:40:38
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 14:02:16
	(b) (4)	

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Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '03 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	07 Dec 2020 15:09:00
User entered empty.	Jo-Ann Rammal (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:02:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 14:02:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:25
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:02:16
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'None (NONE)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:09:00
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:02:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 14:02:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:39
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 14:02:16
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Along with the chest heaviness (see AE log line 2) had a headache. This also was not present at the time of the visit to the PCP on 05 oct 2020, however it was still present on the day 50 safety call on 01 oct 2020.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:09:00
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 14:02:16

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. 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)	18 Jan 2021 04:45:09
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Pericardial disorders NEC, PT: Pericardial effusion, LLT: Pericardial effusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:09:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:09:54
Data point term sent to Coder	System	14 Jan 2021 19:12:56
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Related to pericardial effusion not to cardiac muscle' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 19:12:36
User entered 'UPPER ABDOMEN/chest DISCOMFORT (Related to pericardial effusion)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:12:04
Data point term sent to Coder	System	14 Jan 2021 18:24:55
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:23:58
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:23:58
User entered 'UPPER ABDOMEN DISCOMFORT (CHEST PAIN Cardiac related)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:23:58

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 00:53:31
	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Abdominal discomfort, LLT: Upper abdominal discomfort - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 07:44:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Dec 2020 07:44:43
Data point term sent to Coder	System	07 Dec 2020 15:39:30
User entered 'UPPER ABDOMEN DISCOMFORT (Chest Pain)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	07 Dec 2020 15:38:48
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	07 Dec 2020 15:14:06
	Sharon Mathys (b) (4)	07 Dec 2020 15:13:28
	(b) (4)	
User entered 'Upper Abdomen Discomfort' reason for change: Data Entry Error	Sharon Mathys (b) (4)	07 Dec 2020 15:13:28
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLG: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 15:44:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 15:44:23
Data point term sent to Coder	System	25 Nov 2020 15:43:19
User entered 'Chest pain'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'		25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '15 Nov 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	07 Dec 2020 15:13:28
User entered '16 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
DataPoint Un-verified.	Yaman Ahmed (b) (4)	08 Apr 2021 16:34:38
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4)	08 Apr 2021 16:34:38
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:38:51
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'still ongoing, improving' (Site from DM).	Alayna Wilder (b) (4)	02 Feb 2021 16:09:58
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:28:23
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
DataPoint Un-verified.	Yaman Ahmed (b) (4)	08 Apr 2021 16:34:38
	(b) (4)	
User entered '16 Feb 2021' reason for change: New Information	Yaman Ahmed (b) (4)	08 Apr 2021 16:34:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'None (NONE)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 14:29:36
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Overlaps with SAE, please see narrative. No good way to document' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:24:22
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:53:45
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 05:38:20
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'A diagnostic procedure is still an concomitant procedure. clarify if only medical treatments are asked for here or should be documented' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:26:11
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:53:39
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:38:48
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
DataPoint Un-verified.	Yaman Ahmed (b) (4)	08 Apr 2021 16:34:38
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Yaman Ahmed (b) (4)	08 Apr 2021 16:34:38
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Sharon Mathys (b) (4)	07 Dec 2020 15:41:06
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	25 Nov 2020 15:43:12

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Folder: Adverse Events

Form: Adverse Events (4)

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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)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:43:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: SAE Narrative = ORDERED AN ECHOCARDIOGRAM on 18NOV2020. 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) (4), (b) (6)	19 Jan 2021 09:02:29
User closed query 'Per DM CLR: SAE Narrative = ORDERED LABS (CBC/METAB PROFILE, THYROID SCREEN) on 16NOV2020. However, these were 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 06:07:24
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 19:12:04

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PASSED OUT 15 NOV 2020 AFTER FEELING NAUSEOUS AND GOING ON KNEES. HR VARIED 81-117, DISCOMFORT IN UPPER ABDOMEN SIMILAR TO RIGHT-SIDED CHEST PAIN FROM PREVIOUS. PRESSURE WHEN BENDING OVER AND A FLEETING FLUTTERING SENSATION IN ABDOMEN.WENT TO PCP 16 NOV2020 , PULSE AT VISIT 114 BPM. ORDERED LABS (CBC/METAB PROFILE, THYROID SCREEN), ECG 12 LEAD. ORDERED CT. .CT SCAN CAME BACK WITH NEW MODERATE PERICARDIAL EFFUSION WITH DIFFUSE PERICARDIAL ENHANCEMENT. AND NEW SMALL BILATERAL PLEURAL EFFUSIONS LEFT GREATER THAN RIGHT. HAD CARDIOLOGY CONSULT 18NOV2020. STARTED ON COLCHICINE AND HIGH INTENSITY ASPIRIN BASED ON PREVIOUS CT SCAN RESULT. ORDERED AN ECHOCARDIOGRAM, BNP, TROPONIN I, ANA SCREEN AND TITER, ERTHROCYTE SEDIMINTATION RATE. LATER WENT TO HOSPITAL 26 NOV2020 DUE TO PAIN, DISCHARGED ON 01 DEC 2020. UNBLINDED FROM STUDY. WENT TO PCP ON 04 DEC 2020 AND DID NOT REPORT PAIN THEN. Spoke with patient again 14-Jan-2021 who states that she still has occasional chest/abdominal pain that is likely related to the fluid around her heart. It is significantly better than before, and she is in the processing of coming off of prednisone.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:12:04
Query 'Per DM CLR: SAE Narrative = ORDERED LABS (CBC/METAB PROFILE, THYROID SCREEN) on 16NOV2020. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Recorded for other SAE's that overlap, please see those' (Site from DM).	Sharon Mathys (b) (4)	14 Jan 2021 18:25:23

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = ORDERED AN ECHOCARDIOGRAM on 18NOV2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Recorded in SAEs, please see those' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:25:10
User opened query 'Per DM CLR: SAE Narrative = ORDERED AN ECHOCARDIOGRAM on 18NOV2020. 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 00:53:23
User opened query 'Per DM CLR: SAE Narrative = ORDERED LABS (CBC/METAB PROFILE, THYROID SCREEN) on 16NOV2020. However, these were 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 00:52:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PASSED OUT 15 NOV 2020 AFTER FEELING NAUSEOUS AND GOING ON KNEES. HR VARIED 81-117, DISCOMFORT IN UPPER ABDOMEN SIMILAR TO RIGHT-SIDED CHEST PAIN FROM PREVIOUS. PRESSURE WHEN BENDING OVER AND A FLEETING FLUTTERING SENSATION IN ABDOMEN.WENT TO PCP 16 NOV2020 , PULSE AT VISIT 114 BPM. ORDERED LABS (CBC/METAB PROFILE, THYROID SCREEN), ECG 12 LEAD. ORDERED CT. .CT SCAN CAME BACK WITH NEW MODERATE PERICARDIAL EFFUSION WITH DIFFUSE PERICARDIAL ENHANCEMENT. AND NEW SMALL BILATERAL PLEURAL EFFUSIONS LEFT GREATER THAN RIGHT. HAD CARDIOLOGY CONSULT 18NOV2020. STARTED ON COLCHICINE AND HIGH INTENSITY ASPIRIN BASED ON PREVIOUS CT SCAN RESULT. ORDERED AN ECHOCARDIOGRAM, BNP, TROPONIN I, ANA SCREEN AND TITER, ERTHROCYTE SEDIMINTATION RATE. Later went to hospital 26 nov2020 due to pain, discharged on 01 dec 2020. Unblinded from study. Went to PCP on 04 dec 2020 and did not report pain then.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:41:06
User entered 'Passed out 15 nov 2020 after feeling nauseous and going on knees. HR varied 81-117, discomfort in upper abdomen similar to right-sided chest pain from previous. Pressure when bending over and a fleeting fluttering sensation in abdomen.Went to PCP 16 nov2020 , pulse at visit 114 bpm. Ordered labs (CBC/Metab profile, thyroid screen), ECG 12 lead. Ordered CT. .CT scan came back with new moderate pericardial effusion with diffuse pericardial enhancement. and new small bilateral pleural effusions left greater than right. Had Cardiology consult 18nov2020. Started on colchicine and high intensity aspirin based on previous ct scan result. Ordered an echocardiogram, BNP, Troponin I, ANA screen and titer, Erthrocyte sedimentation rate.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:38:48

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Passed out' reason for change: Data Entry Error	Sharon Mathys (b) (4)	07 Dec 2020 15:13:28
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:43:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 15:43:12

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:38
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:09:02
User entered	System	30 Nov 2020 16:34:07
'USA-US131-2020-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	30 Nov 2020 16:34:07

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:42:40
User coded data point as SOC: Cardiac disorders, HLT: Pericardial disorders, HLT: Pericardial disorders NEC, PT: Pericardial effusion, LLT: Pericardial effusion - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 15:45:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 15:45:25
Data point term sent to Coder	System	25 Nov 2020 15:44:24
User entered 'Pericardial Effusion'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:42
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:49
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (reported as chest pain on 16 Nov 2020).' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 14:04:54
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (reported as chest pain on 16 Nov 2020).' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:17:26
User entered '16 Nov 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:17:16
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (reported as chest pain on 16 Nov 2020).' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:41:25
User entered '18 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:42:51
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Apr 2021 16:20:00
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:20:00
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 16:20:00
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Apr 2021 16:19:11
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:42:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed 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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:58:04
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. Please do not respond to query until end date is known.' answered with 'new baseline' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 16:20:09
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	06 Apr 2021 16:20:00
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	06 Apr 2021 16:20:00
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	06 Apr 2021 16:19:11
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:19:11
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 16:19:11
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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:50:45
User closed 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)	03 Feb 2021 16:07:08

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

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.' answered with 'as of Nov 26 2020, Cardiologist reports improvement.' (Site from Safety). DataPoint Verified.	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 16:07:25
	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	04 Dec 2020 16:39:59
	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

Severity

Audit	User	Time (GMT)
User closed query 'Per source review, it was indicated that condition was moderate pericardial effusion. Please kindly review and advise.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 18:41:22
	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
User closed query 'If grade changed for same condition due to hospitalization, please capture change in separate AE log line.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 05:13:15
Query 'If grade changed for same condition due to hospitalization, please capture change in separate AE log line.' answered with 'We have been asked to merge aes under one term by dm queries if possible so we are keeping separate unless we have guidance from data management team otherwise' (Site from CRA).	Sharon Mathys (b) (4)	01 Feb 2021 15:52:13
	(b) (4)	
Query 'Per source review, it was indicated that condition was moderate pericardial effusion. Please kindly review and advise.' answered with 'Moderate but did require hospitalization a few days later. By the time it was reported it would be considered grade 4' (Site from CRA).	Sharon Mathys (b) (4)	01 Feb 2021 15:51:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User opened query 'If grade changed for same condition due to hospitalization, please capture change in separate AE log line.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:01:24
User opened query 'Per source review, it was indicated that condition was moderate pericardial effusion. Please kindly review and advise.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 19:45:06
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Dec 2020 20:17:16
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:45:08
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	25 Nov 2020 15:46:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:46:41
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	25 Nov 2020 15:46:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:45:13
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:45:15
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:03:29
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 16:07:39
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:54:02
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:01:30
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).		02 Dec 2020 14:04:09
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).		02 Dec 2020 14:04:09
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	02 Dec 2020 14:02:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error Sharon Mathys	(b) (4)	02 Dec 2020 14:02:54
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:01:32
User entered '26 Nov 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 14:02:54
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:01:34
User entered '01 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 14:02:54
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:01:37
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Dec 2020 14:04:09
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:01:39
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:01:44
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:01:46
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:01:47
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:01:50
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:20:50
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' answered with 'Based on the timing of the start of Chest Pain 5 days after dosing, and later diagnosis with etiology matching that of an inflammatory response, Co investigator believes there is a possible relationship between IP and the pericardial effusion occurring' (Site from Safety).	Sharon Mathys (b) (4)	10 Dec 2020 19:51:03
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:50:31
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 14:02:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:01:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:20
User closed query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:20:57
Query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	10 Dec 2020 15:03:33
User opened query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:47:57
User closed query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:08:46
Query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:28:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:17:16
User opened query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:39:38
User entered 'None (NONE)'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:23
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:24
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc #70 indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc #70 indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:23:05
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc #70 indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'Are you talking about thoracentesis? changed to adverse event' (Site from DM).	Sharon Mathys (b) (4)	26 Feb 2021 14:27:17
User entered '1' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 14:26:43
DataPoint Un-verified.	Sharon Mathys (b) (4)	26 Feb 2021 14:25:28
User entered '0' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc #70 indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	Sharon Mathys (b) (4)	26 Feb 2021 14:25:28
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:48:05
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'changed to medical' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 09:38:17
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'changed to medical' (Site from DM).	Alayna Wilder (b) (4)	02 Feb 2021 16:08:03
	(b) (4)	

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Form: Adverse Events (5)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 11:29:17
	(b) (4), (b) (6)	05 Jan 2021 20:02:25
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Dec 2020 20:17:16
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' answered with 'new baseline' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:58:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 16:20:12
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 16:20:00
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:51:01
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' answered with 'cardiologist reports improvement as of 11/26/20' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:07:22
DataPoint Un-verified.	Alayna Wilder (b) (4)	02 Feb 2021 16:09:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Alayna Wilder (b) (4)	02 Feb 2021 16:08:58
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	Alayna Wilder (b) (4)	02 Feb 2021 16:08:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	05 Jan 2021 20:02:28
	(b) (4), (b) (6)	04 Dec 2020 16:40:52
	(b) (4), (b) (6)	25 Nov 2020 15:49:04
	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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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)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:30
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:44:22

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Narrative = EPIGASTRIC PAIN. However, please review and verify if this should 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)	01 Mar 2021 06:42:04
Query 'Per DM CLR: Narrative = EPIGASTRIC PAIN. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'This is recorded under the ae of gerd that came up during that time.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	26 Feb 2021 14:27:00
User opened query 'Per DM CLR: Narrative = EPIGASTRIC PAIN. However, please review and verify if this should 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 23:47:42
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 19:32:00

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '15NOV2020 PARTICIPANT PASSED OUT AFTER KNEELING ON FLOOR AFTER NAUSEAU SPELL. FELT CHEST HEAVINESS/PAIN AS PREVIOUSLY REPORTED. PRESSURE WHEN LEANING FORWARD. HR OBSERVED BETWEEN 84-117. 16NOV2020 WENT TO PCP. HR 114. ORDERED CBC, COMP. METABOLISM, THYROID, AND 12 LEAD EKG. CT SCAN ORDERED, PERFORMED ON 17NOV2020. INITIALLY THOUGHT TO BE POSSIBLY RELATED TO HISTORY OF AORTIC ECTASIA, THORACIC. HIGH INTENSITY ASPIRIN WAS RECOMMENDED. CT SCAN SHOWED MODERATE PERICARDIAL EFFUSION AND SMALL BILATERAL PLEURAL EFFUSIONS. ORDERED ECHOCARDIOGRAM, REVEALS CIRCUMFERENTIAL PERICARDIAL EFFUSION. ETIOLOGY DETERMINED REACTIVE (VIRAL OR INFLAMMATORY). COLCHICINE IS ADDED TWICE A DAY. BNP, TROPONIN, ANA, AND ESR LABS REQUESTED. PAIN CONTINUED IN CHEST ALONG WITH RISING FATIGUE AND EPIGASTRIC PAIN, WENT TO ER ON 26 NOV 2020. LABS ORDERED CBC AND DIFF.. BASIC METAB, BNP, TROPONIN 1, MAGNESIUM, ESR, PROCALCITONIN. CT CHEST WITH IV CONTRAST PULMONARY EMBOLISM DONE, WAS NEGATIVE FOR PE. PERICARDIAL EFFUSION WAS MILD TO MODERATE. 27 NOV 2020, ECHOCARDIOGRAM ORDERED, PERICARDIAL EFFUSION SEEN AS TRIVIAL. MEDICATIONS CHANGED IS HIGH INTENSITY ASPIRIN DISCONTINUED AND COLCHICINE FOR 3 MONTHS AND PREDNISONE TAPER. Patient saw cardiologist 13-Jan-2021 who recommended continuing to taper predisone and noted no pericardial rub on exam though she does still have occasional chest/upper abdominal pain that is likely related to the pericardial fluid. She will follow up with cardiology again in April 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:32:00

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:02:39
User closed query 'PV Query: Please provide hospital records, including laboratory and diagnostic exam results, from the subject's September 2020 emergency room visit due to chest pain and shortness of breath shortly after second dose of study drug with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 15:25:55
Query 'PV Query: Please provide hospital records, including laboratory and diagnostic exam results, from the subject's September 2020 emergency room visit due to chest pain and shortness of breath shortly after second dose of study drug with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' answered with 'redacted Hospital Records for the 15Sep2020 visit with labs and cts have been sent.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	30 Dec 2020 15:06:33
User opened query 'PV Query: Please provide hospital records, including laboratory and diagnostic exam results, from the subject's September 2020 emergency room visit due to chest pain and shortness of breath shortly after second dose of study drug with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:51:03
User closed query 'PV Query: Was a COVID test performed during the September 2020 emergency room visit? If yes, please provide date, type of test, and results.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 17:14:12
User closed query 'PV Query: Please provide hospital records, including laboratory and diagnostic exam results, from the subject's September 2020 emergency room visit due to chest pain and shortness of breath shortly after second dose of study drug.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 17:14:07

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Was a COVID test performed during the September 2020 emergency room visit? If yes, please provide date, type of test, and results.' answered with 'No covid test was ordered for the sep 2020 ER visit' (Site from Safety).	Sharon Mathys (b) (4)	28 Dec 2020 15:33:57
Query 'PV Query: Please provide hospital records, including laboratory and diagnostic exam results, from the subject's September 2020 emergency room visit due to chest pain and shortness of breath shortly after second dose of study drug.' answered with 'Please clarify whether you want anonymized records sent to safety@iqvia or whether you want copied and pasted narrative from previous line into this box, in which case we may run out of room.' (Site from Safety).	Sharon Mathys (b) (4)	28 Dec 2020 15:33:08
User opened query 'PV Query: Was a COVID test performed during the September 2020 emergency room visit? If yes, please provide date, type of test, and results.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:20:44
User opened query 'PV Query: Please provide hospital records, including laboratory and diagnostic exam results, from the subject's September 2020 emergency room visit due to chest pain and shortness of breath shortly after second dose of study drug.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:20:31
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:17:32
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)	18 Dec 2020 21:17:01
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)	18 Dec 2020 14:22:54

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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 'lab and diagnostic tests were sent to safety_moderna@iqvia.com' (Site from Safety).	Jelena Verkler (b) (4)	16 Dec 2020 19:01:02
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:50:43

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '15NOV2020 PARTICIPANT PASSED OUT AFTER KNEELING ON FLOOR after nauseau spell. FELT CHEST HEAVINESS/PAIN AS PREVIOUSLY REPORTED. PRESSURE WHEN LEANING FORWARD. HR OBSERVED BETWEEN 84-117. 16NOV2020 WENT TO PCP. HR 114. ORDERED CBC, COMP. METABOLISM, THYROID, AND 12 LEAD EKG. CT SCAN ORDERED, PERFORMED ON 17NOV2020. INITIALLY THOUGHT TO BE POSSIBLY RELATED TO HISTORY OF AORTIC ECTASIA, THORACIC. HIGH INTENSITY ASPIRIN WAS RECOMMENDED. CT SCAN SHOWED MODERATE PERICARDIAL EFFUSION AND SMALL BILATERAL PLEURAL EFFUSIONS. ORDERED ECHOCARDIOGRAM, REVEALS CIRCUMFERENTIAL PERICARDIAL EFFUSION. ETIOLOGY DETERMINED REACTIVE (VIRAL OR INFLAMMATORY). COLCHICINE IS ADDED TWICE A DAY. BNP, TROPONIN, ANA, AND ESR LABS REQUESTED. PAIN CONTINUED IN CHEST ALONG WITH RISING FATIGUE AND EPIGASTRIC PAIN, WENT TO ER ON 26 NOV 2020. LABS ORDERED CBC AND DIFF.. BASIC METAB, BNP, TROPONIN 1, MAGNESIUM, ESR, PROCALCITONIN. CT CHEST WITH IV CONTRAST PULMONARY EMBOLISM DONE, WAS NEGATIVE FOR PE. PERICARDIAL EFFUSION WAS MILD TO MODERATE. 27 NOV 2020, ECHOCARDIOGRAM ORDERED, PERICARDIAL EFFUSION SEEN AS TRIVIAL. Medications changed is high intensity aspirin discontinued and colchicine for 3 months and prednisone taper.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:26:36

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Update: 15Nov2020 participant passed Sharon Mathys out after kneeling on floor. Felt chest heaviness/pain as previously reported. Pressure when leaning forward. HR observed between 84-117. 16Nov2020 went to PCP. HR 114. Ordered CBC, Comp. Metabolism, Thyroid, and 12 lead EKG. CT scan ordered, performed on 17Nov2020. Initially thought to be possibly related to history of Aortic ectasia, thoracic. High intensity aspirin was recommended. CT scan showed moderate pericardial effusion and small bilateral pleural effusions. Ordered Echocardiogram, reveals circumferential pericardial effusion. Etiology determined reactive (viral or inflammatory). Colchicine is added twice a day. BNP, Troponin, ANA, and ESR labs requested. Pain continued in chest along with rising fatigue and epigastric pain, went to ER on 26 nov 2020. Labs ordered CBC and diff.. basic metab, bnp, troponin 1, magnesium, ESR, procalcitonin. CT chest with IV contrast pulmonary embolism done, was negative for PE. Pericardial effusion was mild to moderate. 27 nov 2020, echocardiogram ordered, pericardial effusion seen as trivial. ' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 17:57:03
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)	04 Dec 2020 16:41:04
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)	04 Dec 2020 16:40:20

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT STATES SHE SAW PCP ON MONDAY 16 NOV FOR CHEST PAIN SHE WAS EXPERIENCING. REFERRED TO CARDIOLOGIST FOR TESTING THAT WAS DONE ON 18 NOV AND DIAGNOSED WITH PERICARDITIS AND PERICARDIAL EFFUSION. Went to the ER for Chest pain on 26Nov2020 and was discharge on 01Dec2020. Study team requesting to unblind. More documentation to come.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Dec 2020 14:04:09
User entered 'PT STATES SHE SAW PCP ON MONDAY 16 NOV FOR CHEST PAIN SHE WAS EXPERIENCING. REFERRED TO CARDIOLOGIST FOR TESTING THAT WAS DONE ON 18 NOV AND DIAGNOSED WITH PERICARDITIS AND PERICARDIAL EFFUSION. SHE HAD JUST SPOKEN WITH DR.RAMESH ABOUT EVENTS BEFORE I CALLED HER. AWAITING COVID TEST AND MAINTAINING CONTACT WITH STUDY TEAM. Continued in redcap' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:49:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Nov 2020 15:45:46
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Nov 2020 15:45:46
User entered 'Pt states she saw PCP on Monday 16 NOV for chest pain she was experiencing. Referred to cardiologist for testing that was done on 18 NOV and diagnosed with pericarditis and pericardial effusion. She had just spoken with Dr.Ramesh about events before I called her. Awaiting COVID test and maintaining contact with study team' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:45:46
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Nov 2020 15:44:22
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 15:46:41
User entered '0'	System	25 Nov 2020 15:46:18
User entered '1'	System	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 15:44:22

US3522109

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 14:04:09

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:50
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:09:02
User entered	(b) (4), (b) (6)	30 Nov 2020 16:35:29
'USA-US131-2020-mRNA-1273-P301000011'		

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:51
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:49:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:49:28
Data point term sent to Coder	System	25 Nov 2020 15:48:25
User entered 'Pericarditis'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:55
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 15:48:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 15:48:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:48:37
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 15:48:10
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:57
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:02:59
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (reported as chest pain on 16 Nov 2020).' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 14:05:27
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (reported as chest pain on 16 Nov 2020).' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:18:06
User entered '16 Nov 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:17:59
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (reported as chest pain on 16 Nov 2020).' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:41:42
User entered '18 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:01
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 11:51:08
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'new baseline' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 16:20:48
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:20:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 16:20:44
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 20:22:17
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:03:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:20:44
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 16:20:44
User closed 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)	03 Feb 2021 16:08:15
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.' answered with 'Visit on 1/18 with physician notes she is still presenting with serositis (pericarditis and small bilateral pleural effusion)' (Site from Safety).	Alayna Wilder (b) (4)	02 Feb 2021 16:13:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
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)	04 Dec 2020 16:43:33
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please do not respond to query until end date is known.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:15:02
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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:51:27
User entered empty.	System	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

Severity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'If grade changed for same condition during the periods of hospitalization, please capture change in separate AE log line.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 05:12:48
User closed query 'Per source review, it was indicated that condition started out at a moderate grade. Please kindly review and advise.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 07:31:13
Query 'If grade changed for same condition during the periods of hospitalization, please capture change in separate AE log line.' answered with 'updated' (Site from CRA).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 16:05:52
Query 'Per source review, it was indicated that condition started out at a moderate grade. Please kindly review and advise.' answered with 'updated' (Site from CRA).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 16:05:46
DataPoint Un-verified.	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 16:05:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 16:05:35
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User opened query 'If grade changed for same condition during the periods of hospitalization, please capture change in separate AE log line.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:04:39
User opened query 'Per source review, it was indicated that condition started out at a moderate grade. Please kindly review and advise.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:04:02
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Dec 2020 14:04:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:03:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:04:41
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:04:43
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:04:45
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 14:04:54
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:04:46
User entered '26 Nov 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 14:04:54
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:04:53
User entered '01 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 14:04:54
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:04:55
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Dec 2020 14:04:54
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:04:56
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:06
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:08
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:09
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:05:11
User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:21:40
Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' answered with 'Based on the timing of the start of Chest Pain 5 days after dosing, and later diagnosis with etiology matching that of an inflammatory response, Co investigator believes there is a possible relationship between IP and the pericarditis occurring' (Site from Safety).	Sharon Mathys (b) (4)	10 Dec 2020 19:51:53
User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:50:14
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 14:04:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:12
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:17
User closed query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:21:38
Query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	10 Dec 2020 15:03:14
User opened query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:48:21
User closed query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:09:09
Query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 20:54:31
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 20:32:37
User opened query 'PV Query: As both vaccine doses were already given, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:43:47
User entered 'None (NONE)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:21
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

US3522109

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:22
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc #70 indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc #70 indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 03:16:39
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc #70 indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'Unchecking, but please confirm. Conproc 70 is diagnostic and has always been diagnostic' (Site from DM).	Sharon Mathys (b) (4)	05 Mar 2021 14:10:57
DataPoint Un-verified.	(b) (4)	
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	05 Mar 2021 14:10:32
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc #70 indication is MEDICAL HISTORY and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:49:37
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 05:04:22
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Alayna Wilder (b) (4)	02 Feb 2021 16:06:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:54:22
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:24
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Dec 2020 20:18:43
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' answered with 'new baseline' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:58:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 16:20:51
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 16:20:44
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. Please do not respond to query until end date is known.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:51:58
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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:51:48
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:51:42
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:51:42
DataPoint Un-verified.	Alayna Wilder (b) (4)	03 Feb 2021 16:07:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 16:06:28
	Alayna Wilder (b) (4)	02 Feb 2021 16:06:20
	(b) (4)	02 Feb 2021 16:06:20

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:25
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:43:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:27
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:48:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:26:59
User entered 'PT STATES SHE SAW PCP ON MONDAY 16 NOV FOR CHEST PAIN SHE WAS EXPERIENCING. REFERRED TO CARDIOLOGIST FOR TESTING THAT WAS DONE ON 18 NOV AND DIAGNOSED WITH PERICARDITIS AND PERICARDIAL EFFUSION. WENT TO THE ER FOR CHEST PAIN ON 26NOV2020 AND WAS DISCHARGE ON 01DEC2020. STUDY TEAM REQUESTING TO UNBLIND. MORE DETAILED INFORMATION ON TESTS IN PERICARDIAL EFFUSION LOG LINE. APPEARS TO HAVE BEEN RESPONSIBLE FOR EPISODIC ATRIAL FLUTTER. Patient saw cardiologist 16-DEC-2020 and again 13-JAN-2021. Cardiology notes that she is symptomatically much better with the prednisone, only occasional chest/upper abdomen pain, no pericardial rub, will continue with a slow prednisone taper and discontinue. Will follow up again with rheumatology in later Jan 2021 and cardiology in April 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:26:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:28
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:17:46
User closed query 'PV Query: Please provide the office visit notes from the Cardiologist including laboratory and diagnostic results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 14:23:15
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)	18 Dec 2020 14:23:09

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 14:23:06
Query 'PV Query: Please provide the office visit notes from the Cardiologist including laboratory and diagnostic results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' answered with 'Cardiologist notes were sent to safety_moderna@iqvia.com' (Site from Safety).	Jelena Verkler (b) (4)	16 Dec 2020 19:02:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'lab and diagnostic tests were sent to safety_moderna@iqvia.com' (Site from Safety).	Jelena Verkler (b) (4)	16 Dec 2020 19:01:39
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'discharge summary was sent to safety_moderna@iqvia.com' (Site from Safety).	Jelena Verkler (b) (4)	16 Dec 2020 19:01:35
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)	11 Dec 2020 19:21:48

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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 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 'Treatments from the hospital visits and labs are currently in rave as diagnositic or mixed between pericarditis and pericardial effusion. Still under monitoring.' (Site from Safety).	Sharon Mathys (b) (4)	10 Dec 2020 19:59:02
User opened query 'PV Query: Please provide the office visit notes from the Cardiologist including laboratory and diagnostic results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:51:08
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:50:58
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)	08 Dec 2020 20:49:17
User entered 'PT STATES SHE SAW PCP ON MONDAY 16 NOV FOR CHEST PAIN SHE WAS EXPERIENCING. REFERRED TO CARDIOLOGIST FOR TESTING THAT WAS DONE ON 18 NOV AND DIAGNOSED WITH PERICARDITIS AND PERICARDIAL EFFUSION. WENT TO THE ER FOR CHEST PAIN ON 26NOV2020 AND WAS DISCHARGE ON 01DEC2020. STUDY TEAM REQUESTING TO UNBLIND. MORE detailed information on tests in pericardial effusion log line. Appears to have been responsible for episodic atrial flutter. Cardiology follow up scheduled on 16 dec 2020.' reason for change: Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:19:40

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
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)	04 Dec 2020 16:42:56
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:42:43
User entered 'PT STATES SHE SAW PCP ON MONDAY 16 NOV FOR CHEST PAIN SHE WAS EXPERIENCING. REFERRED TO CARDIOLOGIST FOR TESTING THAT WAS DONE ON 18 NOV AND DIAGNOSED WITH PERICARDITIS AND PERICARDIAL EFFUSION. Went to the ER for Chest pain on 26Nov2020 and was discharge on 01Dec2020. Study team requesting to unblind. More documentation to come.' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Dec 2020 14:04:54
User entered 'PT STATES SHE SAW PCP ON MONDAY 16 NOV FOR CHEST PAIN SHE WAS EXPERIENCING. REFERRED TO CARDIOLOGIST FOR TESTING THAT WAS DONE ON 18 NOV AND DIAGNOSED WITH PERICARDITIS AND PERICARDIAL EFFUSION. SHE HAD JUST SPOKEN WITH DR.RAMESH ABOUT EVENTS BEFORE I CALLED HER. AWAITING COVID TEST AND MAINTAINING CONTACT WITH STUDY TEAM. Continued in redcap' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:48:37
User entered 'Pt states she saw PCP on Monday 16 NOV for chest pain she was experiencing. Referred to cardiologist for testing that was done on 18 NOV and diagnosed with pericarditis and pericardial effusion. She had just spoken with Dr.Ramesh about events before I called her. Awaiting COVID test and maintaining contact with study team'	(b) (4), (b) (6)	25 Nov 2020 15:48:10

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Folder: Adverse Events

Form: Adverse Events (6)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 15:48:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 15:48:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 14:04:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 20:24:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 20:24:03
Data point term sent to Coder	System	04 Dec 2020 20:23:11
User entered 'Gastro-esophageal Reflux Disease'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '01 Dec 2020'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
DataPoint Un-verified.	Yaman Ahmed (b) (4)	08 Apr 2021 16:36:00
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4)	08 Apr 2021 16:36:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	04 Dec 2020 20:22:33
	(b) (4)	

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Form: Adverse Events (7)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
DataPoint Un-verified.	Yaman Ahmed (b) (4)	08 Apr 2021 16:36:00
	(b) (4)	
User entered '22 Feb 2021' reason for change: New Information	Yaman Ahmed (b) (4)	08 Apr 2021 16:36:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4)	04 Dec 2020 20:22:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #9, 12 and 14 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 14:38:21
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #9, 12 and 14 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'Diagnosis was on 01 dec 2020, so it is the only date, however meds given in hospital to treat likely GERD. No good way to document' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 17:55:25
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #9, 12 and 14 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:54:35
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
DataPoint Un-verified.	Yaman Ahmed (b) (4)	08 Apr 2021 16:36:00
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Yaman Ahmed (b) (4)	08 Apr 2021 16:36:00
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sharon Mathys (b) (4)	04 Dec 2020 20:22:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 16:36:00
	(b) (4)	
User entered 'OBSERVED DURING HOSPITALIZATION VISIT, WAS MENTIONED ONLY ON DISCHARGE ON 01DEC2020. Was given for while on prednisone only. Ended when prednisone was discontinued on 22 Feb 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	08 Apr 2021 16:36:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
	(b) (4)	
User entered 'Observed during hospitalization visit, was mentioned only on discharge on 01dec2020'	Sharon Mathys (b) (4)	04 Dec 2020 20:22:33
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Dec 2020 20:22:33

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 14:40:08
(Site from DM). Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4), (b) (6)	14 Jan 2021 19:34:13
(Site from DM). answered with 'Covid test 25-Nov-2020 was negative' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4), (b) (6)	04 Jan 2021 08:45:44
(Site from DM). User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 15:44:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 15:44:02
Data point term sent to Coder	System	07 Dec 2020 15:43:33
User entered 'Fatigue'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 19:34:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:34:46
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	07 Dec 2020 15:42:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 19:34:46
	(b) (4), (b) (6)	
User entered '2 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:34:46
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	07 Dec 2020 15:42:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Related (RELATED)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

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Folder: Adverse Events

Form: Adverse Events (8)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 19:34:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	14 Jan 2021 19:34:46
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4)	07 Dec 2020 15:42:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'FOLLOWS THE NARRATIVE FOR ABDOMINAL DISCOMFORT/CHEST PAIN ON 15 NOV 2020. FELT FATIGUED AND CONTINUES TO REPORT VARIOUS LEVELS OF FATIGUE UNTIL 04 DEC 2020. COVID Swab test done on 25 nov 2020 and was negative.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:45:35
User entered 'Follows the narrative for abdominal discomfort/chest pain on 15 nov 2020. Felt fatigued and continues to report various levels of fatigue until 04 dec 2020'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 15:42:43

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 15:46:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 15:46:22
Data point term sent to Coder	System	07 Dec 2020 15:44:33
User entered 'Nausea'	Sharon Mathys (b) (4)	07 Dec 2020 15:44:11
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 15:44:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 15:44:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:22
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 15:44:11
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 15:44:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 15:44:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:22
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 15:44:11
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Bout of nausea reported to PCP on 16 nov 2020 as started on 15 nov 2020. Appears to have gone away.'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 15:44:11

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:56
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:45:27
User entered 'USA-US131-2020-mRNA-1273-P301000011'	(b) (4), (b) (6)	08 Dec 2020 20:44:16

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:57
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:45:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 12:45:53
Data point term sent to Coder	System	08 Dec 2020 14:24:20
User entered 'Episodic Atrial Flutter'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:59
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:00
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:02
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:03
User entered '26 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Jan 2021 18:28:27
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 18:28:27
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:28:27
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Jan 2021 18:28:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 14:23:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 14:23:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:23:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 14:23:26
User entered empty.	Sharon Mathys (b) (4)	08 Dec 2020 14:23:26
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed 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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:26:04
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. Please do not respond to query until end date is known.' answered with 'End date has been updated' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 18:29:04
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 18:28:09
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:28:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:07
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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:20:07
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:12
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '26 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '01 Dec 2020'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #11 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 07:00:19
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #11 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'Updated to include line 11' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 18:43:24
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 18:42:14
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:42:14
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #11 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:50:58
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '1'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 18:42:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:42:14
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4)	08 Dec 2020 14:23:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	(b) (4)	15 Jan 2021 13:26:08
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' answered with 'Final outcome updated' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 18:29:55
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 18:28:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:28:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:19:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4)	08 Dec 2020 14:23:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'EPISODIC ATRIAL FLUTTER OBSERVED DURING TELEMETRY DURING HOSPITAL VISIT. NOT SEEN AS A CONCERN, VIEWED AS RELATED TO THE PERICARDITIS (SEE OTHER AE). WAS GIVEN METOPROLOL TARTRATE 25 MG. NOT OBSERVED DURING PCP CHECK UP AFTER HOSPITALIZATION ON 04 DEC 2020. ALSO NOT OBSERVED OR REPORTED ON VISIT TO CARDIOLOGIST 13-JAN-2021. HAS NOT HAD ANY SYMPTOMS SINCE HOSPITALIZATION. Is still taking metoprolol as a precaution but likely that is not long term. Cardiologist believes irritation from the pericarditis was what caused the afib, and that it has resolved now.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:15:46
User entered 'EPISODIC ATRIAL FLUTTER OBSERVED DURING TELEMETRY DURING HOSPITAL VISIT. NOT SEEN AS A CONCERN, VIEWED AS RELATED TO THE PERICARDITIS (SEE OTHER AE). Was given metoprolol tartrate 25 mg. NOT OBSERVED DURING PCP CHECK UP AFTER HOSPITALIZATION ON 04 DEC 2020. ALSO NOT OBSERVED OR REPORTED ON VISIT TO CARDIOLOGIST 13-JAN-2021. HAS NOT HAD ANY SYMPTOMS SINCE HOSPITALIZATION.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:42:14
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 18:28:09
User entered 'EPISODIC ATRIAL FLUTTER OBSERVED DURING TELEMETRY DURING HOSPITAL VISIT. NOT SEEN AS A CONCERN, VIEWED AS RELATED TO THE PERICARDITIS (SEE OTHER AE). NOT OBSERVED DURING PCP CHECK UP AFTER HOSPITALIZATION ON 04 DEC 2020. Also not observed or reported on visit to cardiologist 13-Jan-2021. Has not had any symptoms since hospitalization.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 18:28:09

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Episodic Atrial Flutter observed during telemetry during hospital visit. Not seen as a concern, viewed as related to the Pericarditis (see other AE). Not observed during PCP check up after hospitalization on 04 dec 2020.'	Sharon Mathys (b) (4)	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Dec 2020 14:23:26

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 20:46:09
User entered 'USA-US131-2020-mRNA-1273-P301000011'	(b) (4), (b) (6)	08 Dec 2020 20:46:02

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Bilateral pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:52:14
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 20:52:14
Data point term sent to Coder	System	08 Dec 2020 14:36:28
User entered 'Pleural Effusions (Bilateral)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '17 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 14:35:56

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 13:21:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:21:45
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	08 Dec 2020 14:35:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed 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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:05:52
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. Please do not respond to query until end date is known.' answered with '22-FEB-2021 END DATE' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 13:23:38
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	09 Mar 2021 13:23:16
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:23:16
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	09 Mar 2021 13:21:45
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 13:21:45
User entered '22 Feb 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:21:45
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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:52:48
User closed 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. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:09:03
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. Please do not respond to query until end date is known.' answered with 'Visit with physician on 1/18/21 reports still presenting with serositis (pericarditis and small bilateral pleural effusion). Following up with cardiology.' (Site from Safety).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 16:15:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
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. Please do not respond to query until end date is known.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	18 Dec 2020 21:18:40
	Sharon Mathys (b) (4)	08 Dec 2020 14:35:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 14:35:56

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '26 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '01 Dec 2020'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Related (RELATED)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		08 Dec 2020 14:41:41
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:41:41
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	08 Dec 2020 14:35:56
User entered '1'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:05:58
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' answered with 'RECEOVERED/RESOVLED' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 13:23:46
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 13:21:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:21:45
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved. Please do not respond to query until end date is known.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:52:59
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:52:44
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:19:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'NEW SMALL PLEURAL EFFUSIONS (BILATERAL, LEFT GREATER THAN RIGHT) OBSERVED IN CT SCAN PERFORMED ON 17 NOV 2020. AFTER GOING TO HOSPITAL ON 26NOV2020 (SEE PERICARDIAL EFFUSION NARRATIVE), CT FOUND THAT THERE WAS A MILD TO MODERATE LEFT AND SMALL RIGHT PLEURAL EFFUSION. THORACENTESIS PERFORMED ON 30 NOV2020 ON THE MODERATE LEFT PLEURAL EFFUSION REMOVING 450 CC OF CLEAR YELLOW FLUID WHICH WAS ANALYZED AND FOUND NEGATIVE FOR BACTERIA/FUNGI. NO NEW IMAGING ON FILE AFTER 30NOV2020. PARTICIPANT DEEMED STABLE AND RELEASED FROM HOSPITAL. AS OF 04DEC2020 IS NOT REPORTING SHORTNESS OR BREATH OR PLEURODYNIA. APPOINTMENT WITH CARDIOLOGY ON 16DEC2020 AND 13 JAN 2021. NOTED ON PERICARDIAL RUB ON EXAM BUT NO REPEAT IMAGING WAS ORDERED. 22-FEB-2021 weaned off of Prednisone, asymptomatic with no shortness of breath or chest pain. No pulmonology follow up appointment schedule at this time.' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:25:13
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 19:37:31

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'NEW SMALL PLEURAL EFFUSIONS (BILATERAL, LEFT GREATER THAN RIGHT) OBSERVED IN CT SCAN PERFORMED ON 17 NOV 2020. AFTER GOING TO HOSPITAL ON 26NOV2020 (SEE PERICARDIAL EFFUSION NARRATIVE), CT FOUND THAT THERE WAS A MILD TO MODERATE LEFT AND SMALL RIGHT PLEURAL EFFUSION. THORACENTESIS PERFORMED ON 30 NOV2020 ON THE MODERATE LEFT PLEURAL EFFUSION REMOVING 450 CC OF CLEAR YELLOW FLUID WHICH WAS ANALYZED AND FOUND NEGATIVE FOR BACTERIA/FUNGI. NO NEW IMAGING ON FILE AFTER 30NOV2020. PARTICIPANT DEEMED STABLE AND RELEASED FROM HOSPITAL. AS OF 04DEC2020 IS NOT REPORTING SHORTNESS OR BREATH OR PLEURODYNIA. APPOINTMENT WITH CARDIOLOGY on 16DEC2020 and 13 Jan 2021. Noted on pericardial rub on exam but no repeat imaging was ordered.'	(b) (4), (b) (6)	14 Jan 2021 19:37:31
reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'New small Pleural effusions (bilateral, left greater than right) observed in CT scan performed on 17 nov 2020. After going to hospital on 26nov2020 (see pericardial effusion narrative), CT found that there was a mild to moderate left and small right pleural effusion. Thoracentesis performed on 30 nov2020 on the moderate left pleural effusion removing 450 cc of clear yellow fluid which was analyzed and found negative for bacteria/fungi. No new imaging on file after 30nov2020. Participant deemed stable and released from hospital. As of 04dec2020 is not reporting shortness or breath or pleurodynia. Next appointment with cardiology is 16dec2020 which may have imaging to determine whether it has resolved.'	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Dec 2020 14:35:56

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma in situ, LLT: Melanoma in situ - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 04:38:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 04:38:05
Data point term sent to Coder	System	10 Dec 2020 21:33:36
User entered 'Melanoma in situ (left shoulder)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '22 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '5 Nov 2020'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'None (NONE)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Mar 2021 12:56:52
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 12:56:52
	(b) (4), (b) (6)	09 Mar 2021 12:56:52
User entered '1' reason for change: Data Entry Error	System	09 Mar 2021 12:56:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).		
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4)	10 Dec 2020 21:33:32
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR-RQ: Response noted. Procedures are to be recorded in Con Proc ecrf. However, this field is ticked if therapeutic procedures/surgeries are given. The recorded procedures associated are diagnostic procedures. Consider updating this field to NO or provide therapeutic surgeries in con proc ecrf. Else, re-clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 06:44:23
Query 'Per DM CLR-RQ: Response noted. Procedures are to be recorded in Con Proc ecrf. However, this field is ticked if therapeutic procedures/surgeries are given. The recorded procedures associated are diagnostic procedures. Consider updating this field to NO or provide therapeutic surgeries in con proc ecrf. Else, re-clarify.' answered with 'Diagnositc' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 12:56:21
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 12:56:21
User opened query 'Per DM CLR-RQ: Response noted. Procedures are to be recorded in Con Proc ecrf. However, this field is ticked if therapeutic procedures/surgeries are given. The recorded procedures associated are diagnostic procedures. Consider updating this field to NO or provide therapeutic surgeries in con proc ecrf. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 02:07:39
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 06:17:13

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' answered with 'We were asked us to enter the procedure' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 19:36:02
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	14 Jan 2021 00:51:12
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'SHE HAD A SKIN CHECK WITH DERMATOLOGY IN 22 OCT 2020 AND TWO LESIONS WERE DISCOVERED. A LESION ON LEFT SHOULDER WAS BIOPSIED ON 05 NOV 2020 AND WAS MELANOMA IN SITU WITH CLEAR MARGINS AND DID NOT REQUIRE TREATMENT; A SECOND ON THE LEFT CHEEK WAS ACTINIC KERATOSIS AND SHE RECEIVED RED-LIGHT TREATMENT FOR IT ON 13 NOV 2020.' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:56
User entered 'For the recent diagnosis of Melanoma in Situ (not in EPIC yet?): She had a skin check with Dermatology in 22 Oct 2020 and two lesions were discovered. A lesion on left shoulder was biopsied on 05 Nov 2020 and was Melanoma in situ with clear margins and did not require treatment; a second on the left cheek was Actinic Keratosis and she received red-light treatment for it on 13 Nov 2020.'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Dec 2020 21:33:32

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 21:43:52
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 21:43:52
Data point term sent to Coder	System	10 Dec 2020 21:36:37
User entered 'Actinic Keratosis (left cheek)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '22 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '13 Nov 2020'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 21:36:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 21:36:13
User entered 'None (NONE)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:13
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 21:36:06
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Per Narrative, SHE RECEIVED RED-LIGHT TREATMENT FOR IT ON 13 NOV 2020. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 06:52:58
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Per Narrative, SHE RECEIVED RED-LIGHT TREATMENT FOR IT ON 13 NOV 2020. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:41:35
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Diagnostic and not Adverse Event. Per Narrative, SHE RECEIVED RED-LIGHT TREATMENT FOR IT ON 13 NOV 2020. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 00:51:29
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'I'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	Sharon Mathys (b) (4)	14 Jan 2021 18:39:18
	(b) (4)	
User entered 'SHE HAD A SKIN CHECK WITH DERMATOLOGY IN 22 OCT 2020 AND TWO LESIONS WERE DISCOVERED. A LESION ON LEFT SHOULDER WAS BIOPSIED ON 05 NOV 2020 AND WAS MELANOMA IN SITU WITH CLEAR MARGINS AND DID NOT REQUIRE TREATMENT; A SECOND ON THE LEFT CHEEK WAS ACTINIC KERATOSIS AND SHE RECEIVED RED-LIGHT TREATMENT (photodynamic therapy) FOR IT ON 13 NOV 2020.'	Sharon Mathys (b) (4)	14 Jan 2021 18:39:18
	(b) (4)	
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:09:17
User entered 'She had a skin check with Dermatology in 22 Oct 2020 and two lesions were discovered. A lesion on left shoulder was biopsied on 05 Nov 2020 and was Melanoma in situ with clear margins and did not require treatment; a second on the left cheek was Actinic Keratosis and she received red-light treatment for it on 13 Nov 2020.'	Yaman Ahmed (b) (4)	10 Dec 2020 21:36:06
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Dec 2020 21:36:06

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:48:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:48:47
Data point term sent to Coder	System	19 Apr 2021 17:47:53
User entered 'Fatigue'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '13 Sep 2020'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '18 Sep 2020'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Related (RELATED)'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'I'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sharon Mathys (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	19 Apr 2021 17:46:56
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 17:46:56

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:49:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 17:49:40
Data point term sent to Coder	System	19 Apr 2021 17:48:55
User entered 'Myalgia'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '17 Sep 2020'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '17 Sep 2020'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered '0'	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Related (RELATED)'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered 'I'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	19 Apr 2021 17:48:12
	(b) (4)	

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:00:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sharon Mathys (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Apr 2021 19:00:13
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 17:48:12

US3522109

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 08:01:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 17:48:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:01:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	09 Sep 2020 14:05:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:15:59

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 14:08:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:08:56
Data point term sent to Coder	System	09 Sep 2020 14:08:06
Data point term sent to Coder	System	09 Sep 2020 14:07:02
User entered 'Naproxen'	Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:06:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Knee pain' reason for change: Data Entry Error	Sharon Mathys (b) (4)	09 Sep 2020 14:07:12
	(b) (4)	
User entered 'Generalized Pain'	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '500'	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'mg (mg)'	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'other (OTHER)'	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'twice daily with food as needed'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:06:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '1'	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	09 Sep 2020 14:06:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 14:06:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 14:06:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 14:06:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE RHA 4V (BACULOVIRUS), PRODUCTSYNONYM: FLUBLOK QUADRIVALENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:48:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP).' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:59:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE RHA 3V (BACULOVIRUS), PRODUCTSYNONYM: FLUBLOK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:23:39
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 16:23:39
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP).' answered with 'recorded incorrectly, date/dose confirmed in medical record ' (Site from DM).	Alandra White (b) (4) (b) (4)	22 Oct 2020 16:22:39
Data point term sent to Coder	System	22 Oct 2020 16:22:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Alandra White (b) (4)	22 Oct 2020 16:22:08
	(b) (4)	
User entered 'FluBlok RIV4' reason for change: Data Entry Error	Alandra White (b) (4)	22 Oct 2020 16:22:08
	(b) (4)	
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:07:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 15:11:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 15:11:42
	(b) (4)	
Data point term sent to Coder	System	03 Oct 2020 15:10:33
Coding entries removed.	Sharon Mathys (b) (4)	03 Oct 2020 15:09:54
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:18:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:18:50
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 13:36:31
User entered 'Flu vaccine'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	03 Oct 2020 15:09:54
User entered 'No (N)'	(b) (4)	
	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'flu prevention' reason for change:	(b) (4)	
Data Entry Error	Sharon Mathys (b) (4)	03 Oct 2020 15:09:54
User entered 'UK'	(b) (4)	
	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0.5' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	22 Oct 2020 16:22:08
User entered 'UK'	(b) (4)	
	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	22 Oct 2020 16:23:00
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	22 Oct 2020 16:22:08
User entered 'mL (mL)' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	22 Oct 2020 16:22:08
User entered 'Other (OTHER)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alandra White (b) (4)	22 Oct 2020 16:23:00
User entered 'UK'	(b) (4)	
	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once (ONCE)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Intramuscular (INTRAMUSCULAR)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	22 Oct 2020 16:22:08
User entered '10 Sep 2020'	(b) (4)	
	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Alandra White (b) (4)	22 Oct 2020 16:22:08
User entered '10 Sep 2020'	(b) (4)	
	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User entered empty.	System	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User entered empty.	System	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:27
User entered empty.	System	01 Oct 2020 13:35:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: PROVENTIL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Jan 2021 21:04:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:04:23
Data point term sent to Coder	System	29 Jan 2021 13:29:50
Coding entries removed.	(b) (4), (b) (6)	29 Jan 2021 13:29:33
User entered 'ALBUTEROL (PROVENTIL) NEBULIZER SOLUTION' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:29:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: PROVENTIL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 12:36:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 12:36:13
Data point term sent to Coder	System	03 Oct 2020 15:11:33
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:10:52
User entered 'ALBUTEROL (PROVENTIL) 2.5 MG /3 ML (0.083 %) NEBULIZER SOLUTION' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	03 Oct 2020 15:10:52

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: PROVENTIL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:19:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:19:46
Data point term sent to Coder	System	01 Oct 2020 13:59:09
User entered 'albuterol (PROVENTIL) 2.5 mg /3 mL (0.083 %) nebulizer solution (Order 477834345)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:58:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 05:52:56
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 15:49:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 15:49:41
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 15:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:59:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:59:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:59:00
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:58:33
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:58:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:59:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 13:59:00
User entered 'Asthma' reason for change: Data Entry Error	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:59:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 13:58:33
User entered empty.	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage. (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 12:05:48
User entered '2.5/3/0.083' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:29:59
Query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage. answered with 'updated to reflect' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:29:45
User entered '2.5/3/0.083 %' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:29:33
User opened query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage. (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:48:59
User entered '2'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:58:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:29:33
User entered 'mL (mL)'	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:58:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg/ml/%' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:29:33
User entered empty.	Jo-Ann Rammal (b) (4) (b) (4)	01 Oct 2020 13:58:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'as needed (PRN)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	03 Oct 2020 15:10:33
	(b) (4)	
User entered '30 Sep 2020'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	03 Oct 2020 15:10:33
	(b) (4)	
User entered '0'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'No (N)'	Jo-Ann Rammal (b) (4)	01 Oct 2020 13:58:33
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:58:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:58:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:58:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Dec 2020 14:44:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 14:44:43
Data point term sent to Coder	System	07 Dec 2020 14:43:43
Coding entries removed.	Sharon Mathys (b) (4)	07 Dec 2020 14:43:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Oct 2020 13:28:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 13:28:24
Data point term sent to Coder	System	09 Oct 2020 12:00:29
User entered 'Fluticasone'	Alandra White (b) (4)	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'No (N)'	Alandra White (b) (4)	09 Oct 2020 11:59:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR-RQ: Response noted. Please review if the associated medical diagnosis of sinus congestion should be recorded in MH/AE ecrf. If there is no associated condition, consider recording this event in MH/AE ecrf. Else, provide further clarification is this event will not be recorded. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:28:28
Query 'Per DM CLR-RQ: Response noted. Please review if the associated medical diagnosis of sinus congestion should be recorded in MH/AE ecrf. If there is no associated condition, consider recording this event in MH/AE ecrf. Else, provide further clarification is this event will not be recorded. ' answered with 'congestion is related to participants seasonal allergies which is listed in MH' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:54:14
User opened query 'Per DM CLR-RQ: Response noted. Please review if the associated medical diagnosis of sinus congestion should be recorded in MH/AE ecrf. If there is no associated condition, consider recording this event in MH/AE ecrf. Else, provide further clarification is this event will not be recorded. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 02:04:11
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR-RQ: Response noted. However, Sinus Congestion is not recorded in MH or AE ecrf. Review and update appropriate eCRF accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 04:25:04
Query 'Per DM CLR-RQ: Response noted. However, Sinus Congestion is not recorded in MH or AE ecrf. Review and update appropriate eCRF accordingly.' answered with 'Sinus congestion is not typically a medical dx.' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	05 Jan 2021 16:02:29
User opened query 'Per DM CLR-RQ: Response noted. However, Sinus Congestion is not recorded in MH or AE ecrf. Review and update appropriate eCRF accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 08:49:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 10:48:05
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'updated' (Site from DM).	Alayna Wilder (b) (4)	18 Dec 2020 15:25:09
User entered 'SINUS CONgestion' reason for change: Data Entry Error	(b) (4)	07 Dec 2020 14:43:26
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 15:12:08
User entered 'sinus conjestion'	Alandra White (b) (4)	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 06:17:39
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:31:11
User entered '50' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:31:04
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:50:30
User entered '1'	Alandra White (b) (4) (b) (4)	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:24:06
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:31:04
User entered 'puff (PUFF)'	Alandra White (b) (4) (b) (4)	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 07:58:15
Query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:24:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:24:06
User opened query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:14:39
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:31:04
User entered empty.	Alandra White (b) (4) (b) (4)	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'as needed (PRN)'	Alandra White (b) (4)	09 Oct 2020 11:59:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Alandra White (b) (4) (b) (4)	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Nasal (NASAL)'	Alandra White (b) (4)	09 Oct 2020 11:59:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Alandra White (b) (4)	09 Oct 2020 11:59:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '5 Oct 2020'	Alandra White (b) (4)	09 Oct 2020 11:59:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '0'	Alandra White (b) (4)	09 Oct 2020 11:59:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Yes (Y)'	Alandra White (b) (4)	09 Oct 2020 11:59:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Alandra White (b) (4) (b) (4)	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 12:00:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 12:00:05
User entered 'No (N)' reason for change: Data Entry Error	Alandra White (b) (4)	09 Oct 2020 12:00:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 11:59:58
User entered empty.	Alandra White (b) (4)	09 Oct 2020 11:59:58
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 11:59:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN EC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 18:35:19
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 Nov 2020 18:35:19
Data point term sent to Coder	System	25 Nov 2020 15:53:31
User entered 'aspirin EC'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered 'pericarditis'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered '650'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered '18 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 05:04:55
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 15:31:53
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 15:31:49
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 15:31:49
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:49:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User entered '2'	System	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User entered '1'	System	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:42
User entered '804 (804)'	System	25 Nov 2020 15:53:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:37:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:37:00
Data point term sent to Coder	System	08 Dec 2020 14:46:37
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:46:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN EC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 18:35:19
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 Nov 2020 18:35:19
Data point term sent to Coder	System	25 Nov 2020 15:55:34
User entered 'aspirin EC'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered 'PERICARDITIS/ Pericardial Effusion'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:02
reason for change: Data Entry Error	(b) (4)	
User entered 'pericarditis'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered '650'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered 'mg (mg)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:45:51
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	07 Dec 2020 14:42:43
User entered 'Other (OTHER)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:42:43
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	25 Nov 2020 15:55:18
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:45:51
User entered 'Pt to change to 81 mg aspirin following 1 week on this current dose. 81 mg to start on 2 DEC 2020 and continue'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:45:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered '01 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:45:51
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 05:05:10
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 15:35:39
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 15:32:14
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 15:32:14
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:49:23

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User entered '1'	System	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User entered '1'	System	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:45
User entered '804 (804)'	System	25 Nov 2020 15:55:18

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:58:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:58:10
Data point term sent to Coder	System	25 Nov 2020 15:57:36
User entered 'Colchicine'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered 'pericarditis'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered '0.6'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered 'twice daily (BID)'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per CDM: Please verify data and reconcile medication start date on this form with start date indicated in Narrative on Log Line 5 of AE form. If appropriate, consider updating start date of this medication to 25Nov, else confirm correct. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 07:16:47
Query 'Per CDM: Please verify data and reconcile medication start date on this form with start date indicated in Narrative on Log Line 5 of AE form. If appropriate, consider updating start date of this medication to 25Nov, else confirm correct. Thank you.' answered with 'This is correct, was given at visit with cardiologist before going to hospital at 25 nov' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	20 Jan 2021 15:17:09
User opened query 'Per CDM: Please verify data and reconcile medication start date on this form with start date indicated in Narrative on Log Line 5 of AE form. If appropriate, consider updating start date of this medication to 25Nov, else confirm correct. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:38:51
Query 'Per CDM: Please verify start date of this medication and reconcile start date on this form with Narrative on Log Line 5 of AE form. If appropriate, consider updating start date of this medication to 25Nov, else confirm correct. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:37:34
User opened query 'Per CDM: Please verify start date of this medication and reconcile start date on this form with Narrative on Log Line 5 of AE form. If appropriate, consider updating start date of this medication to 25Nov, else confirm correct. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:37:19
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered '18 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered '0'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Un-verified.	Sharon Mathys (b) (4)	19 Jan 2021 15:14:44
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	19 Jan 2021 15:14:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 15:57:33

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 07:16:26
	(b) (4), (b) (6)	05 Jan 2021 20:06:08
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'Medication prescribed in Nov, Screening was Sept. This was not 6 months prior to screening.' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	05 Jan 2021 16:00:36
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 09:46:01
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)	11 Dec 2020 13:19:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 13:19:51
Data point term sent to Coder	System	07 Dec 2020 19:42:09
User entered 'Prednisone'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered 'Pericarditis'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '40' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	29 Jan 2021 13:43:28
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 13:32:21
User entered '40 MG X7 DAYS, 35 MG X7 DAYS, 30 MG X7 DAYS, 25 MG X7DAYS, 25 MG X7 DAYS, 20 MG X7 DAYS, 20 MG X7 DAYS, 10 MG X 7 DAYS, 5 MG X 7 DAYS' (non-conformant).	(b) (4), (b) (6)	29 Jan 2021 13:32:21
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered 'un' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	08 Dec 2020 14:44:31
User entered '40'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:32:21
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:32:21
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered 'Other (OTHER)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:44:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 05:02:45
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 13:32:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 13:32:21
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:53:12
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 19:41:59
User entered '40 MG X7 DAYS. 35 MG X7 DAYS, 30 MG X7 DAYS, 25 MG X7DAYS, 25 MG X7 DAYS, 20 MG X7 DAYS, 20 MG X7 DAYS, 10 mg x 7 days, 5 mg x 7 days' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 19:41:59
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered '40 mg X7 DAYS. 35 MG X7 DAYS, 30 MG X7 DAYS, 25 MG X7DAYS, 25 MG X7 DAYS, 20 MG X7 DAYS, 20 MG X7 DAYS' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:44:56
User entered 'X7 DAYS. 35 MG X7 DAYS, 30 MG X7 DAYS, 25 MG X7DAYS, 25 MG X7 DAYS, 20 MG X7 DAYS, 20 MG X7 DAYS' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:44:31
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered 'once daily (QD)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:44:31
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:43:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	08 Dec 2020 14:44:31
User entered 'x7 days. 35 mg x7 days, 30 mg x7 days, 25 mg x7days, 25 mg x7 days, 20 mg x7 days, 20 mg x7 days' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:43:34
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 13:31:07
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:31:07
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:31:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 20:31:37
User entered '01 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Un-verified.	(b) (4)	
	Sharon Mathys (b) (4)	29 Jan 2021 13:43:28
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:43:28
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:43:34
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:42:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:42:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:42:15
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:42:03
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:31:07
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:31:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '06 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:50:31
User entered '05 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:49:06
DataPoint Un-verified.	Sharon Mathys (b) (4)	29 Jan 2021 13:43:28
User entered '07 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:43:28
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	07 Dec 2020 19:43:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:43:34
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	07 Dec 2020 19:42:03
User entered '08 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:08
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User entered '1'	System	08 Dec 2020 14:44:31
User entered empty.	System	07 Dec 2020 19:43:34
User entered '1'	System	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User entered '1'	System	08 Dec 2020 14:44:31
User entered empty.	System	07 Dec 2020 19:43:34
User entered '1'	System	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:56
User entered '804 (804)'	System	08 Dec 2020 14:44:31
User entered empty.	System	07 Dec 2020 19:43:34
User entered '804 (804)'	System	07 Dec 2020 19:42:03

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:32:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:32:51
Data point term sent to Coder	System	07 Dec 2020 20:32:13
Data point term sent to Coder	System	07 Dec 2020 19:46:11
User entered 'Protonix'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered 'Gastro Esophageal Reflux Disease' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 20:31:16
User entered 'prophylaxis for ulcer'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered '40'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered '29 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 20:31:16
User entered '02 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 16:37:28
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 16:37:28
User entered 'No (N)' reason for change: New Information	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
DataPoint Un-verified.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 16:37:28
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	08 Apr 2021 16:37:28
User entered '22 Feb 2021' reason for change: New Information	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:14
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User entered '1'	System	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User entered '1'	System	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:02
User entered '804 (804)'	System	07 Dec 2020 19:45:38

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE;ZINC ACETATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Jan 2021 22:53:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 22:53:30
Data point term sent to Coder	System	29 Jan 2021 16:23:05
Coding entries removed.	Alayna Wilder (b) (4) (b) (4)	29 Jan 2021 16:22:38
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:15
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE;ZINC ACETATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:32:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:32:48
Data point term sent to Coder	System	07 Dec 2020 19:55:21
User entered 'Diphenhydramine-zinc acetate'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 05:03:09
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	29 Jan 2021 16:22:45
DataPoint Un-verified.	Alayna Wilder (b) (4) (b) (4)	29 Jan 2021 16:22:38
User entered 'ITCHING secondary to seasonal allergies' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	29 Jan 2021 16:22:38
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:50:03
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'Itching'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'topical application'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'as needed (PRN)'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered '01 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 19:55:19

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: This Conmed is given for the AE#10 EPISODIC ATRIAL FLUTTER. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. '(Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 06:18:32
Query 'Per DM CLR: This Conmed is given for the AE#10 EPISODIC ATRIAL FLUTTER. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:57:54
User opened query 'Per DM CLR: This Conmed is given for the AE#10 EPISODIC ATRIAL FLUTTER. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. '(Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:51:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 15:18:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 15:18:43
Data point term sent to Coder	System	07 Dec 2020 19:48:12
Data point term sent to Coder	System	07 Dec 2020 19:46:11
User entered 'Metoprolol Tartrate'	(b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:47:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:47:25
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:46:08
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:47:25
User entered 'Episodic atrial flutter' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:47:25
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:46:08
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '25'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:47:25
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:47:25
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:46:08
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:47:25
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:47:25
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:46:08
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	07 Dec 2020 19:47:25
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:47:25
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	07 Dec 2020 19:46:08
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:47:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:47:25
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:46:08
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 19:47:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 19:47:25
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 19:46:08
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Dec 2020 19:47:25
User entered empty.	System	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 19:47:25
User entered empty.	System	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Dec 2020 19:47:25
User entered empty.	System	07 Dec 2020 19:46:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: MAALOX [ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 17:48:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 17:48:18
Data point term sent to Coder	System	18 Dec 2020 17:35:06
User closed query 'For coding purposes, Please enter the active ingredient(s) in parenthesis after drug name, or specify if unknown, and please make your changes to the reported term.' (Site from System).	System	18 Dec 2020 17:34:46
Query 'For coding purposes, Please enter the active ingredient(s) in parenthesis after drug name, or specify if unknown, and please make your changes to the reported term.' answered with 'added per emr record. This is all the information available' (Site from System).	Sharon Mathys (b) (4)	18 Dec 2020 17:34:46
User entered 'MAALOX PLUS (aluminum and magnesium hydroxide-simethicone)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	18 Dec 2020 17:34:42
Data point term sent to Coder	System	18 Dec 2020 17:29:01
User entered 'MAALOX PLUS (unknown)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	18 Dec 2020 17:28:44
User opened query 'For coding purposes, Please enter the active ingredient(s) in parenthesis after drug name, or specify if unknown, and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	18 Dec 2020 14:39:37
Data point term sent to Coder	System	08 Dec 2020 14:48:39
Data point term sent to Coder	System	07 Dec 2020 20:25:02
Data point term sent to Coder	System	07 Dec 2020 20:09:40

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Maalox plus'	(b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'GASTRO esophageal REFLUX DISEASE' reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Sharon Mathys (b) (4)	08 Dec 2020 14:48:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Gastro intestinal reflux disease' reason for change: Data Entry Error	System	07 Dec 2020 20:24:46
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:24:46
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 20:24:46

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 06:19:22
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'given before actual diagnosis' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:59:14
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:51:06
User entered '26 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User entered empty.	System	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User entered empty.	System	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:34
User entered empty.	System	07 Dec 2020 20:09:04

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:50:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:50:43
Data point term sent to Coder	System	07 Dec 2020 20:28:07
Data point term sent to Coder	System	07 Dec 2020 20:10:41
User entered 'Benadryl'	(b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
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	07 Dec 2020 20:27:17
User entered 'Pericarditis' reason for change: Data Entry Error	System	07 Dec 2020 20:27:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 20:10:13
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '25'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User entered empty.	System	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User entered empty.	System	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:36
User entered empty.	System	07 Dec 2020 20:10:13

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: LIDOCAINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 01:03:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 01:03:55
Data point term sent to Coder	System	07 Dec 2020 20:27:06
Data point term sent to Coder	System	07 Dec 2020 20:25:02
Data point term sent to Coder	System	07 Dec 2020 20:13:46
User entered 'Lidocaine HCL 2% viscous solution'	(b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'GASTRO Esophageal REFLUX DISEASE' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:26:43
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:24:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 20:24:58
User entered 'Gastro intestinal reflux disease' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 20:24:58
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:13:15
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '15'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 06:19:53
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'Given before actual diagnosis' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:58:54
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:51:18
User entered '26 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:51:14
' canceled (Site from DM).		
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.	(b) (4), (b) (6)	21 Jan 2021 20:50:49
' (Site from DM).		
User entered '26 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User entered empty.	System	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User entered empty.	System	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:40
User entered empty.	System	07 Dec 2020 20:13:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:27:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:27:53
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Dec 2020 20:27:06 07 Dec 2020 20:26:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:16:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:16:56
Data point term sent to Coder User entered 'Robaxin'	System (b) (4), (b) (6)	07 Dec 2020 20:15:50 07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected 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) (4), (b) (6)	01 Feb 2021 06:20:22
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'taken during the pericarditis ae' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:59:38
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected 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)	21 Jan 2021 20:53:47
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:26:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 20:26:27
User entered 'Pericarditis' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 20:26:27
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:15:15
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '500'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User entered '4'	System	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User entered '1'	System	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:45
User entered '804 (804)'	System	07 Dec 2020 20:15:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 01:28:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 01:28:51
Data point term sent to Coder	System	07 Dec 2020 20:17:55
User entered 'Lovenox'	(b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Venous thromboembolism prophylaxis'	(b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '40'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User entered '1'	System	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User entered '1'	System	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:51
User entered '804 (804)'	System	07 Dec 2020 20:17:10

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:19:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:19:57
Data point term sent to Coder	System	07 Dec 2020 20:18:55
User entered 'Tylenol'	(b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
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	07 Dec 2020 20:18:39
User entered 'Pericarditis' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 20:18:39
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:18:26
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '650'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'as needed every 6 hours'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User entered empty.	System	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User entered empty.	System	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:17
User entered empty.	System	07 Dec 2020 20:18:26

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:47:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:47:28
Data point term sent to Coder	System	29 Jan 2021 14:07:17
Data point term sent to Coder	System	29 Jan 2021 14:06:17
Coding entries removed.	Sharon Mathys (b) (4)	29 Jan 2021 14:05:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 20:42:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 20:42:57
Data point term sent to Coder	System	07 Dec 2020 20:30:11
User entered 'Potassium Chloride'	(b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 14:05:50
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 12:05:02
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated to prophylactic as there is no underlying condition only standard procedure during hospitalizations of this sort' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:06:56
User entered 'PREVENTION OF ISSUES DURING HOSPITALIZATION: ELECTROLYTE REPLACEMENT' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:06:32
User entered 'Prevention of issues during hospitalization ELECTROLYTE REPLACEMENT' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:05:50
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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:52:08
User entered 'Electrolyte replacement'	(b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '20'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 12:00:31
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' answered with 'updated to meq' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:07:04
User entered 'Other (OTHER)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:05:50
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:52:18
User entered 'IU (IU)'	(b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'meq' reason for change: Data Entry Error	(b) (4)	29 Jan 2021 14:05:50
User entered empty.	Sharon Mathys (b) (4)	07 Dec 2020 20:29:25
	(b) (4), (b) (6)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'twice'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User entered empty.	System	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User entered empty.	System	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:24
User entered empty.	System	07 Dec 2020 20:29:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: CITRIC ACID;POTASSIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:45:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:45:28
Data point term sent to Coder	System	29 Jan 2021 14:08:18
Coding entries removed.	Sharon Mathys (b) (4)	29 Jan 2021 14:08:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: CITRIC ACID;POTASSIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 00:30:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 00:30:42
Data point term sent to Coder	System	07 Dec 2020 20:20:57
User entered 'Potassium bicarb-citric acid'	(b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 14:08:14
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 12:05:13
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated to prophylactic as there is no underlying condition only standard procedure during hospitalizations of this sort' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:09:47
User entered 'PREVENTION OF ISSUES DURING HOSPITALIZATION: ELECTROLYTE REPLACEMENT' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:08:14
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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:51:49
User entered 'Electrolyte replacement'	(b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '20'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query ' Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 12:00:39
Query ' Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' answered with 'updated to meq' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:09:44
User entered 'Other (OTHER)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 14:08:14
User opened query ' Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 20:51:56
User entered 'IU (IU)'	(b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'meq' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 14:08:14
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'twice'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 20:22:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	07 Dec 2020 20:22:19
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	07 Dec 2020 20:20:35
User entered '27 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User entered empty.	System	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User entered empty.	System	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:33
User entered empty.	System	07 Dec 2020 20:20:35

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 00:17:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Dec 2020 00:17:52
Data point term sent to Coder	System	08 Dec 2020 14:57:49
Coding entries removed.	Sharon Mathys (b) (4)	08 Dec 2020 14:57:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:31:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:31:57
Data point term sent to Coder	System	07 Dec 2020 20:31:12
User entered 'Polyethylene glycol'	(b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	08 Dec 2020 14:57:35
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Prevention of CONSTIPATION'	(b) (4)	
reason for change: Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:57:35
User entered 'Constipation'	(b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '17'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User entered empty.	System	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User entered empty.	System	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:37
User entered empty.	System	07 Dec 2020 20:30:40

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:01:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:01:48
Data point term sent to Coder	System	07 Dec 2020 20:33:14
User entered 'Toradol'	(b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'pericarditis'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '15'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User entered empty.	System	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User entered empty.	System	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:41
User entered empty.	System	07 Dec 2020 20:32:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:24:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:24:29
Data point term sent to Coder	System	08 Dec 2020 14:58:50
Coding entries removed.	Sharon Mathys (b) (4)	08 Dec 2020 14:58:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:34:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:34:59
Data point term sent to Coder	System	07 Dec 2020 20:34:14
User entered 'Lactulose'	(b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	08 Dec 2020 14:58:45
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Prevention of CONSTIPATION'	(b) (4)	
reason for change: Data Entry Error	Sharon Mathys (b) (4)	08 Dec 2020 14:58:45
User entered 'Constipation'	(b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '20'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User entered '2'	System	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User entered '1'	System	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:12:46
User entered '804 (804)'	System	07 Dec 2020 20:33:31

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:34:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:34:45
Data point term sent to Coder	System	08 Dec 2020 14:47:39
User entered 'Aspirin'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Pericarditis'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '81'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'mg (mg)'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'once daily (QD)'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '02 Dec 2020'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	08 Dec 2020 14:46:55
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 14:46:55

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 14:46:55

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 14:46:55

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:45:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:45:19
Data point term sent to Coder	System	29 Jan 2021 13:44:53
User entered 'Prednisone'	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Pericarditis'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '35'	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once daily (QD)'	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:31:38
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:31:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '07 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:50:02
User entered '08 Dec 2020'	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:31:38
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:31:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '13 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:50:02
User entered '15 Dec 2020'	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User entered '1'	System	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User entered '1'	System	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:09
User entered '804 (804)'	System	29 Jan 2021 13:44:43

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:49:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:49:18
Data point term sent to Coder	System	29 Jan 2021 13:48:54
User entered 'Prednisone'	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Pericarditis'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30'	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once daily (QD)'	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:31:56
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:31:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '14 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:51:15
User entered '16 Dec 2020'	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:31:56
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:31:56
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	29 Jan 2021 13:51:15
User entered '20 Dec 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:51:15
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	29 Jan 2021 13:48:16
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User entered '1'	System	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User entered '1'	System	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:12
User entered '804 (804)'	System	29 Jan 2021 13:48:16

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:53:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:53:18
Data point term sent to Coder	System	29 Jan 2021 13:52:56
User entered 'Prednisone'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Pericarditis'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '25'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once daily (QD)'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '21 Dec 2020'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '03 Jan 2021' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Jan 2021 13:53:54
User entered '27 Dec 2020'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User entered '1'	System	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User entered '1'	System	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:35
User entered '804 (804)'	System	29 Jan 2021 13:52:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:56:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:56:19
Data point term sent to Coder	System	29 Jan 2021 13:56:00
User entered 'Prednisone'	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Pericarditis'	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '20'	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once daily (QD)'	(b) (4) Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:32:29
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:32:29
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '04 Jan 2021'	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:32:29
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:32:29
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '17 Jan 2021'	Sharon Mathys (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User entered '1'	System	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User entered '1'	System	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:38
User entered '804 (804)'	System	29 Jan 2021 13:55:02

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:57:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Jan 2021 13:57:18
Data point term sent to Coder	System	29 Jan 2021 13:57:01
User entered 'Prednisone'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Pericarditis'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '10'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'mg (mg)'	(b) (4) Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'once daily (QD)'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:34:18
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:34:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '18 Jan 2021'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '0'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 13:34:18
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 13:34:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '24 Jan 2021'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User entered '1'	System	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User entered '1'	System	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:42
User entered '804 (804)'	System	29 Jan 2021 13:56:12

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Jan 2021 13:58:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 13:58:19
Data point term sent to Coder	System	29 Jan 2021 13:58:01
User entered 'Prednisone'	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:57:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Pericarditis'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '5'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'mg (mg)'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:57:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'once daily (QD)'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	29 Jan 2021 13:57:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '25 Jan 2021'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '0'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	29 Jan 2021 16:23:46
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	29 Jan 2021 16:23:46
User entered empty; reason for change Data Entry Error	Alayna Wilder (b) (4)	29 Jan 2021 16:23:46
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	29 Jan 2021 13:57:01
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	29 Jan 2021 13:57:01
User entered '31 Jan 2021'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'No (N)'	Sharon Mathys (b) (4)	29 Jan 2021 13:57:01
	(b) (4)	

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 13:57:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 13:57:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jan 2021 13:57:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 13:34:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:34:55
Data point term sent to Coder	System	09 Mar 2021 13:34:09
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '15'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User entered '1'	System	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User entered '1'	System	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:55
User entered '804 (804)'	System	09 Mar 2021 13:33:36

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 13:51:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:51:55
Data point term sent to Coder	System	09 Mar 2021 13:36:10
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '15'	(b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User entered '1'	System	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User entered '1'	System	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:40
User entered '804 (804)'	System	09 Mar 2021 13:36:07

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:37:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:37:55
Data point term sent to Coder	System	09 Mar 2021 13:37:10
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '10'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '18 Jan 2021'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '25 Jan 2021'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User entered '1'	System	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User entered '1'	System	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User entered '804 (804)'	System	09 Mar 2021 13:37:08

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
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)	09 Mar 2021 13:38:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Mar 2021 13:38:56
Data point term sent to Coder	System	09 Mar 2021 13:38:11
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '12.5'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User entered '1'	System	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User entered '1'	System	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:14
User entered '804 (804)'	System	09 Mar 2021 13:38:00

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:40:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:40:57
Data point term sent to Coder	System	09 Mar 2021 13:40:12
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '10'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '28 Jan 2021'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '31 Jan 2021'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User entered '1'	System	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User entered '1'	System	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:34
User entered '804 (804)'	System	09 Mar 2021 13:39:15

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:40:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Mar 2021 13:40:56
Data point term sent to Coder	System	09 Mar 2021 13:40:12
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '7.5'	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	09 Mar 2021 13:40:10
User entered '03 Feb 2021' reason for change: Data Entry Error	System	09 Mar 2021 13:40:10
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	09 Mar 2021 13:40:01
User entered '03 Jan 2021'	(b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User entered '1'	System	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User entered '1'	System	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:36
User entered '804 (804)'	System	09 Mar 2021 13:40:01

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:43:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Mar 2021 13:43:01
Data point term sent to Coder	System	09 Mar 2021 13:42:18
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '5'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '07 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User entered '1'	System	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User entered '1'	System	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:40
User entered '804 (804)'	System	09 Mar 2021 13:41:25

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 13:43:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Mar 2021 13:43:02
Data point term sent to Coder	System	09 Mar 2021 13:42:20
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '2.5'	(b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '07 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User entered '1'	System	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User entered '1'	System	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:48
User entered '804 (804)'	System	09 Mar 2021 13:42:11

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 13:43:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:43:56
Data point term sent to Coder	System	09 Mar 2021 13:43:21
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '5'	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User entered '1'	System	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User entered '1'	System	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:03
User entered '804 (804)'	System	09 Mar 2021 13:42:57

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 13:44:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:44:55
Data point term sent to Coder	System	09 Mar 2021 13:44:22
User entered 'prednisone'	(b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'pericarditis'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '2.5'	(b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User entered '1'	System	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User entered '1'	System	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:09:23
User entered '804 (804)'	System	09 Mar 2021 13:43:39

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:09:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:09:08
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	25 Mar 2021 17:15:15
Data point term sent to Coder	System	24 Mar 2021 19:57:25
User entered 'Botox-A injection'	Yaman Ahmed (b) (4) (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'No (N)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'Facial Rhytides (glabella and crows feet)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered '28'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'IU (IU)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered empty.	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'once (ONCE)'	(b) (4) Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered empty.	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered empty.	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered '15 Mar 2021'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered '0'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'No (N)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered '15 Mar 2021'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'No (N)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User entered empty.	System	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User entered empty.	System	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:06
User entered empty.	System	24 Mar 2021 19:56:58

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTS SYNONYM: RESTYLANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 10:40:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 10:40:26
Data point term sent to Coder	System	24 Mar 2021 20:00:27
User entered 'Restylane dermal filler'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'No (N)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'cosmetic (face)'	(b) (4) Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'I'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'mL (mL)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered empty.	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'once (ONCE)'	(b) (4) Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered empty.	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered empty.	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered '15 Mar 2021'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered '0'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'No (N)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered '15 Mar 2021'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User signature succeeded.	Marcus Zervos (b) (4)	25 Mar 2021 17:15:15
User entered 'No (N)'	Yaman Ahmed (b) (4)	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User entered empty.	System	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User entered empty.	System	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 08:01:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:19
User entered empty.	System	24 Mar 2021 19:59:28

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:01:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	07 Dec 2020 14:31:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 12:16:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '15 Sep 2020'	Sharon Mathys (b) (4)	07 Dec 2020 14:33:48
	(b) (4)	

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CT chest with IV contrast pulmonary embolism'	(b) (4) Sharon Mathys (b) (4)	07 Dec 2020 14:33:48

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4)	07 Dec 2020 14:33:48

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:33:48

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:50
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '15 Sep 2020'	Sharon Mathys (b) (4)	07 Dec 2020 14:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:50
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CBC and Differential'	Sharon Mathys (b) (4)	07 Dec 2020 14:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:50
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:50
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '15 Sep 2020'	Sharon Mathys (b) (4)	07 Dec 2020 14:41:00

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Basic Metabolic Profile'	Sharon Mathys (b) (4)	07 Dec 2020 14:41:00

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:41:00

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:41:00

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:57
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '15 Sep 2020'	Sharon Mathys (b) (4)	07 Dec 2020 14:41:25

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:57
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Troponin I'	Sharon Mathys (b) (4)	07 Dec 2020 14:41:25

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:57
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:41:25

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:57
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:41:25

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '15 Sep 2020'	Sharon Mathys (b) (4)	07 Dec 2020 14:41:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'PT/INR/PTT'	Sharon Mathys (b) (4)	07 Dec 2020 14:41:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 14:41:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:02
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:41:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '15 Sep 2020'	Sharon Mathys (b) (4)	07 Dec 2020 14:42:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'D-Dimer, Quantitative'	Sharon Mathys (b) (4)	07 Dec 2020 14:42:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 14:42:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	Sharon Mathys (b) (4)	07 Dec 2020 14:42:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:06:37
User entered '17 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 15:20:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:37
User entered 'CT angiography chest gated with iv contrast (**non-coronary**)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:20:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:37
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:20:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:20:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:30
User entered '16 Nov 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	07 Dec 2020 15:23:21
User entered '15 Nov 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:23:14

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:30
User entered 'ECG 12 lead'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:23:14

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:30
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:23:14

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 15:23:14

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:29
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:33
User entered '18 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:58:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:29
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:33
User entered 'BNP'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:58:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:29
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:33
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:58:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:29
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:58:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:40
User entered '18 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:59:16

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:40
User entered 'TROPONIN I' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:59:25
User entered 'Troponin'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:59:16

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:40
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:59:16

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:07:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:40
User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:59:16

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '18 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 17:59:42

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'ANA Screen and Titer'	Sharon Mathys (b) (4)	07 Dec 2020 17:59:42

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:59:42

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:59:42

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:05
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '18 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:00:45

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:05
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Erythrocyte Sedimentation Rate'	Sharon Mathys (b) (4)	07 Dec 2020 18:00:45

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:05
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:00:45

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:05
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:00:45

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '25 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:04:53

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '2019 nCoronavirus, PCR (Covid-19)'	Sharon Mathys (b) (4)	07 Dec 2020 18:04:53

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:04:53

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:04:53

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:05:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CBC and Differential'	Sharon Mathys (b) (4)	07 Dec 2020 18:05:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:05:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:05:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:35:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Basic Metabolic Profile'	Sharon Mathys (b) (4)	07 Dec 2020 18:35:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:35:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:35:22

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'BNP'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:22

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:35:22

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:22

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:35:35

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Troponin I'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:35

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:35

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:35

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:31
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:35:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:31
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Magnesium'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:31
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:31
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:35:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:36:08

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Erythrocyte Sedimentation Rate'	Sharon Mathys (b) (4)	07 Dec 2020 18:36:08

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:08

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:08

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:36:22

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Procalcitonin'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:22

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:22

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:22

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:36:43

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Troponin I'	Sharon Mathys (b) (4)	07 Dec 2020 18:36:43

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:43

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:43

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:36:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Basic Metabolic Profile'	Sharon Mathys (b) (4)	07 Dec 2020 18:36:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:36:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:10
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:37:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:10
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'C-Reactive Protein'	Sharon Mathys (b) (4)	07 Dec 2020 18:37:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:10
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:37:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:10
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:13
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:37:24

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:13
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CBC'	Sharon Mathys (b) (4)	07 Dec 2020 18:37:24

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:13
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:24

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:13
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:24

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:37:42

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Magnesium'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:42

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:42

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:42

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:37:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Phosphorus'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:37:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:26
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:38:14

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:26
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'ANA Screen and Titer'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:38:14

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:26
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:38:14

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:26
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:38:14

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:38:41

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'HIV 4th Generation Antigen/Antibody Combo'	Sharon Mathys (b) (4)	07 Dec 2020 18:38:41

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:38:41

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:38:41

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:39:51

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Blood Culture'	Sharon Mathys (b) (4)	07 Dec 2020 18:39:51

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:39:51

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:39:51

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:40:09

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Histoplasma Ag, Quant'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:09

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:09

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:36
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:09

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:40:24

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Basic Metabolic Profile'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:24

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:24

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:24

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CBC and Differential'	Sharon Mathys (b) (4)	07 Dec 2020 18:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:13:53
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:40:56

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Liver Profile'	Sharon Mathys (b) (4)	07 Dec 2020 18:40:56

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:56

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:40:56

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:50:51

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Magnesium'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:50:51

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:50:51

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:14:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:50:51

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:06
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	07 Dec 2020 18:51:55
User entered '28 Nov 2020' reason for change: Data Entry Error	System	07 Dec 2020 18:51:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Sharon Mathys (b) (4)	07 Dec 2020 18:51:27
User entered '28 Nov 200' (non-conformant).	(b) (4)	07 Dec 2020 18:51:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:06
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'T4, Free'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:51:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:06
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:51:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:06
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:51:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:51:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'TSH'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:51:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:51:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:51:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:52:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Phosphorus'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:52:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:52:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:19
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:52:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (38)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:52:31

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (38)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Respiratory Virus Panel PCR'	Sharon Mathys (b) (4)	07 Dec 2020 18:52:31

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (38)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:52:31

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (38)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:52:31

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (39)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:52:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (39)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Flu A/B and RSV PCR, Nasopharynx'	Sharon Mathys (b) (4)	07 Dec 2020 18:52:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (39)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:52:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (39)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:27
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:52:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (40)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:53:20

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (40)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'PT/INR/PTT'	Sharon Mathys (b) (4)	07 Dec 2020 18:53:20

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (40)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:53:20

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (40)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:53:20

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (41)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '29 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:53:37

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (41)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Basic Metabolic Profile'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:53:37

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (41)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:53:37

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (41)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:53:37

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (42)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '29 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:53:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (42)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CBC and Differential'	Sharon Mathys (b) (4)	07 Dec 2020 18:53:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (42)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:53:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (42)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:53:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (43)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '29 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 18:54:03

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (43)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Magnesium'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:54:03

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (43)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 18:54:03

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (43)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:40
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 18:54:03

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (44)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '29 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:16:11

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (44)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Phosphorus'	Sharon Mathys (b) (4)	07 Dec 2020 19:16:11

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (44)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:16:11

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (44)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:48
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:16:11

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (45)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:16:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (45)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Basic Metabolic Profile'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:16:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (45)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:16:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (45)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:51
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:16:27

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (46)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:00

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (46)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CBC and Differential'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:00

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (46)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:00

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (46)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:54
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:18:00

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (47)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:15

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (47)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'magnesium'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:15

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (47)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:18:15

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (47)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:16:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:18:15

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (48)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:01
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:29

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (48)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:01
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Phosphorus'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:18:29

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (48)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:01
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:18:29

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (48)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:01
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:18:29

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (49)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (49)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Cell Count and Differential, Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (49)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:18:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (49)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:18:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (50)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:22:13

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (50)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Fluid Culture, non-CSF (anaerobic/aerobic) with gram stain'	Sharon Mathys (b) (4)	07 Dec 2020 19:22:13

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (50)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:22:13

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (50)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:07
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:22:13

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (51)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:22:28
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (51)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered 'Protein, Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:22:28
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (51)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4)	07 Dec 2020 19:22:28

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (51)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered empty.	Sharon Mathys (b) (4)	07 Dec 2020 19:22:28
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (53)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:23:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (53)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'LDH, Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:23:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (53)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:23:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (53)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:08
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:23:10

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (54)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:23:29

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (54)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Fungal Culture, Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:23:29

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (54)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:23:29

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (54)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:23:29

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (55)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:23:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (55)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'AFB Culture, Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:23:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (55)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:23:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (55)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:23:52

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (56)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:24:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (56)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Glucose, Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:24:11

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (56)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:24:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (56)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:22
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:24:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (57)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:26
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:24:23

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (57)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:26
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'pH, Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:24:23

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (57)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:26
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:24:23

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (57)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:26
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:24:23

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (58)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:24:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (58)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Adenosine Deaminase, Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:24:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (58)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:24:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (58)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:30
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:24:39

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (59)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:24:57

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (59)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Covid-19 Antibody, IgG'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:24:57

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (59)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:24:57

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (59)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:33
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:24:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (60)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:13

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (60)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Basic Metabolic Profile'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:13

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (60)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:13

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (60)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:25:13

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (61)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:33

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (61)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Magnesium'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:25:33

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (61)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:33

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (61)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:25:33

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (62)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:44

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (62)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Phosphorus'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:44

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (62)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:44

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (62)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4)	07 Dec 2020 19:25:44

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (63)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '01 Dec 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (63)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'LDH, Total'	Sharon Mathys (b) (4)	07 Dec 2020 19:25:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (63)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:25:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (63)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:49
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:25:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (64)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '04 Dec 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:26:20

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (64)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CBC and Differential'	Sharon Mathys (b) (4)	07 Dec 2020 19:26:20

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (64)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:26:20

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (64)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:00
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:26:20

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (65)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '04 Dec 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:26:35

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (65)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'C-Reactive Protein'	Sharon Mathys (b) (4)	07 Dec 2020 19:26:35

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (65)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:26:35

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (65)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:04
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:26:35

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (66)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:52
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '04 Dec 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:26:55

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (66)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:52
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Erythrocyte Sedimentation Rate'	Sharon Mathys (b) (4)	07 Dec 2020 19:26:55

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (66)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:52
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:26:55

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (66)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:52
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:26:55

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (67)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:55
User closed query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #68 ECG (26 NOV 2020). Verify and update dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:53:52
Query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #68 ECG (26 NOV 2020). Verify and update dates or remove duplicate entry as necessary. ' answered with 'two separate ECG's were done on same day. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:51:48
User opened query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #68 ECG (26 NOV 2020). Verify and update dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 09:52:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 14:22:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (67)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:55
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'ecg 12 lead 1 of 2'	(b) (4) Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 14:22:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (67)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:55
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	26 Jan 2021 14:23:06
User entered 'Adverse Event (AE)'	(b) (4)	
	Sharon Mathys (b) (4)	26 Jan 2021 14:22:59
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (67)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:55
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 14:22:59

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (68)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per CDM: Per AE Narrative on AE Log Line 5, subject received standard 12 Lead Electrocardiogram (EKG) in addition to Echocardiogram (ECG). Please verify if subject received more than one echocardiogram (ECG) and more than one standard 12 lead electrocardiogram (EKG), verify the dates of these tests, and update as appropriate in Concomitant Procedures forms. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 05:34:57
Query 'Per CDM: Per AE Narrative on AE Log Line 5, subject received standard 12 Lead Electrocardiogram (EKG) in addition to Echocardiogram (ECG). Please verify if subject received more than one echocardiogram (ECG) and more than one standard 12 lead electrocardiogram (EKG), verify the dates of these tests, and update as appropriate in Concomitant Procedures forms. Thank you.' answered with 'What is recorded is correct. The procedures were recorded with the dates of order.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 14:21:23
User opened query 'Per CDM: Per AE Narrative on AE Log Line 5, subject received standard 12 Lead Electrocardiogram (EKG) in addition to Echocardiogram (ECG). Please verify if subject received more than one echocardiogram (ECG) and more than one standard 12 lead electrocardiogram (EKG), verify the dates of these tests, and update as appropriate in Concomitant Procedures forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:28:35
User entered '26 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:37:50

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (68)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User closed query 'Per CDM: Please review Log Lines 68 and 69 of Concomitant Procedures log. Log Line 68 "Procedure/Surgery" on 26Nov is recorded as 'ECG' and Log Line 69 "Procedure/Surgery" on 26Nov is recorded as 'ECG 12 Lead (Twice)'. Therefore, please verify and if appropriate, update Procedure/Surgery on Log Line 68 to 'ECG 12 Lead, 1 of 2' to indicate 1 of 2 on this date and update Line 69 to 'ECG 12 Lead, 2 of 2' to indicate 2 of 2 on this date. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 06:35:17
Query 'Per CDM: Please review Log Lines 68 and 69 of Concomitant Procedures log. Log Line 68 "Procedure/Surgery" on 26Nov is recorded as 'ECG' and Log Line 69 "Procedure/Surgery" on 26Nov is recorded as 'ECG 12 Lead (Twice)'. Therefore, please verify and if appropriate, update Procedure/Surgery on Log Line 68 to 'ECG 12 Lead, 1 of 2' to indicate 1 of 2 on this date and update Line 69 to 'ECG 12 Lead, 2 of 2' to indicate 2 of 2 on this date. Thank you.' answered with 'updated per procedure. line 67 is ecg 12 lead 1 of 2' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	26 Jan 2021 14:22:45
User opened query 'Per CDM: Please review Log Lines 68 and 69 of Concomitant Procedures log. Log Line 68 "Procedure/Surgery" on 26Nov is recorded as 'ECG' and Log Line 69 "Procedure/Surgery" on 26Nov is recorded as 'ECG 12 Lead (Twice)'. Therefore, please verify and if appropriate, update Procedure/Surgery on Log Line 68 to 'ECG 12 Lead, 1 of 2' to indicate 1 of 2 on this date and update Line 69 to 'ECG 12 Lead, 2 of 2' to indicate 2 of 2 on this date. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 15:17:51
User entered 'ECG'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:37:50

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (68)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:37:50

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (68)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:59
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:37:50

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (69)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:01
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:38:08

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (69)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:01
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'ECG 12 LEAD 2 of 2' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	26 Jan 2021 14:23:15
User entered 'ECG 12 Lead (twice)'	(b) (4)	
	Sharon Mathys (b) (4)	07 Dec 2020 19:38:08
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (69)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:01
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:38:08

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (69)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:01
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:38:08

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (70)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:05
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:38:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (70)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:05
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Telemetry Monitoring (until 01dec2020)'	Sharon Mathys (b) (4)	07 Dec 2020 19:38:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (70)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:05
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:38:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (70)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:05
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:38:39

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (71)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:38:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (71)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'ECG 12 Lead'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:38:54

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (71)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:38:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (71)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:09
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:38:54

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (72)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '28 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:39:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (72)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'ECG 12 Lead'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:39:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (72)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:39:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (72)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:12
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:39:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (73)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:39:28

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (73)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CXR-PAL'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:39:28

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (73)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	Sharon Mathys (b) (4)	07 Dec 2020 19:39:28

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (73)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:15
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:39:28

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (74)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '26 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:39:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (74)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'CT Chest with iv Contrast Pulmonary Embolism'	Sharon Mathys (b) (4)	07 Dec 2020 19:39:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (74)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:39:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (74)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:18
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:39:59

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (75)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:21
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '27 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:40:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (75)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:21
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Echocardiogram'	Sharon Mathys (b) (4)	07 Dec 2020 19:40:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (75)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:21
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:40:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (75)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:21
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:40:12

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (76)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:25
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '29 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (76)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:25
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Chest marking (for Thoracentesis)'	Sharon Mathys (b) (4)	07 Dec 2020 19:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (76)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:25
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4)	07 Dec 2020 19:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (76)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:25
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:40:36

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (77)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:40:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (77)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Thoracentesis'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:40:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (77)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:28
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:32:52
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 10:04:32
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	26 Feb 2021 14:26:20
Signature has been broken.	Sharon Mathys (b) (4) (b) (4)	26 Feb 2021 14:26:12
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	26 Feb 2021 14:26:12
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 09:53:21
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:23:18
User entered 'Medical History (MH)' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 15:52:27
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:40:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (77)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:28
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:40:52

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (78)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:41:44

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (78)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Chest 1 view (including portable)'	Sharon Mathys (b) (4)	07 Dec 2020 19:41:44

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (78)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Adverse Event (AE)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:41:44

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (78)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:34
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:41:44

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (79)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '30 Nov 2020'	Sharon Mathys (b) (4)	07 Dec 2020 19:42:09

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (79)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Cytology Pleural Fluid'	Sharon Mathys (b) (4)	07 Dec 2020 19:42:09

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (79)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:42:09

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (79)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:37
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 19:42:09

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (80)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '13 Nov 2020'	Sharon Mathys (b) (4)	14 Jan 2021 18:41:16

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (80)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Photodynamic Therapy (Red Light)'	Sharon Mathys (b) (4)	14 Jan 2021 18:41:16

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (80)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:41
User closed query 'Per DM CLR: Indication = Medical History. Please review and verify if this was performed for the AE of ACTINIC KERATOSIS (LEFT CHEEK). If yes, please update the indication as appropriate,' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 04:51:43
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
Query 'Per DM CLR: Indication = Medical History. Please review and verify if this was performed for the AE of ACTINIC KERATOSIS (LEFT CHEEK). If yes, please update the indication as appropriate,' answered with 'updated' (Site from DM).	Alayna Wilder (b) (4)	19 Feb 2021 01:30:50
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Alayna Wilder (b) (4)	19 Feb 2021 01:30:28
User opened query 'Per DM CLR: Indication = Medical History. Please review and verify if this was performed for the AE of ACTINIC KERATOSIS (LEFT CHEEK). If yes, please update the indication as appropriate,' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:50:11
User entered 'Medical History (MH)' reason for change: Data Entry Error	Alayna Wilder (b) (4)	02 Feb 2021 15:52:48
User entered 'Adverse Event (AE)'	Sharon Mathys (b) (4)	14 Jan 2021 18:41:16

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (80)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:41
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	14 Jan 2021 18:41:16

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (81)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:44
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '5 Nov 2020'	Yaman Ahmed (b) (4)	10 Dec 2020 21:38:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (81)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:44
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'excision biopsy of left shoulder and left cheek skin lesions'	(b) (4) Yaman Ahmed (b) (4)	10 Dec 2020 21:38:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (81)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:44
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Yaman Ahmed (b) (4)	10 Dec 2020 21:38:10

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (81)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:44
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	10 Dec 2020 21:38:10

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (82)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:28:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (82)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Blepharoplasty'	(b) (4), (b) (6)	09 Mar 2021 13:28:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (82)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'Medical History (MH)'	(b) (4), (b) (6)	09 Mar 2021 13:28:39

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (82)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:48
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 13:28:39

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (83)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:54
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	09 Mar 2021 17:00:33
User entered '02 Mar 2021' reason for change: Data Entry Error	System	09 Mar 2021 17:00:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 17:00:06
User entered 'UN Mar 2021' (non-conformant).	System	09 Mar 2021 17:00:06
	(b) (4), (b) (6)	09 Mar 2021 17:00:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (83)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:54
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
User entered 'DIAGNOSTIC ULTRASOUND BILATERAL HANDS' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:02:24
User entered 'ULTRASOUND BILATERAL HANDS'	(b) (4), (b) (6)	09 Mar 2021 17:00:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (83)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:54
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	09 Mar 2021 17:00:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (83)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:54
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:00:06

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (84)

Generated On: 10 Jun 2021 08:01:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (84)

Generated On: 10 Jun 2021 08:01:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (84)

Generated On: 10 Jun 2021 08:01:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58

US3522109

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (84)

Generated On: 10 Jun 2021 08:01:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:58

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
User entered '30/Nov/2020 11:35'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
User entered '03/Dec/2020 11:27'	System	03 Dec 2020 16:27:57

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 14:06:01
User entered 'I'	(b) (4), (b) (6)	03 Dec 2020 16:27:57

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
User entered '06/Dec/2020 09:06'	System	06 Dec 2020 14:06:09

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:09:23
User entered 'I'	(b) (4), (b) (6)	06 Dec 2020 14:06:09

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
User entered '08/Dec/2020 10:09'	System	08 Dec 2020 15:09:33

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:26:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 15:09:33

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
User entered '08/Dec/2020 15:47'	System	08 Dec 2020 20:47:11

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:26:34
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 20:47:11

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '15/Jan/2021 08:26'	(b) (4) System	15 Jan 2021 13:26:45

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:09:50
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 13:26:45

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered '03/Feb/2021 11:10'	(b) (4) System	03 Feb 2021 16:10:08

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 14:02:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:10:08

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:32:52
User entered '01/Mar/2021 09:02'	(b) (4) System	01 Mar 2021 14:02:20

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:59:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:32:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:02:20

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered '08/Mar/2021 14:59'	(b) (4) System	08 Mar 2021 14:59:29

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:57:51
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:59:29

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
User entered '10/Mar/2021 09:57'	(b) (4) System	10 Mar 2021 14:57:43

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:15:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 14:57:51
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 14:57:43

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'USA-US131-2020-MRNA-1273-P301000011'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
Un-reviewed for Safety.	System	02 Dec 2020 14:02:54
User entered 'Yes (Y)'	System	02 Dec 2020 14:02:54
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'No (N)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Yes (Y)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Paul'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'Kilgore'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6) '	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered 'MI'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:35:43
User entered (b) (6)'	System	30 Nov 2020 16:34:07

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 16:27:41
User entered 'US'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 08:01:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	07 Apr 2021 13:14:02
User entered '10'	System	10 Mar 2021 14:57:43
User entered '9'	System	08 Mar 2021 14:59:29
User entered '8'	System	01 Mar 2021 14:02:20
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:23:18
	(b) (4)	
User entered '7'	System	03 Feb 2021 16:10:08
User entered '6'	System	15 Jan 2021 13:26:45
User entered '5'	System	08 Dec 2020 20:47:11
User entered '4'	System	08 Dec 2020 15:09:33
User entered '3'	System	06 Dec 2020 14:06:09
User entered '2'	System	03 Dec 2020 16:27:57
User entered '1'	System	30 Nov 2020 16:35:51

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 08:01:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered '07/Apr/2021 06:13'	(b) (4) System	07 Apr 2021 13:14:02

US3522109

Folder: SAE USA-US131-2020-MRNA-1273-P301000011

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 08:01:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:53:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:14:02