

US3592247 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:23:30

All time stamps listed in this document are displayed in GMT

US3592247

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 09:44:21

Generated On: 10 Jun 2021 08:23:30

[Participant ID](#)

US3592247

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

US3592247

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	29 AUG 2020

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

Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Date of Birth (MMM yyyy)	(b) (6) 1933
Age	87
Age Units	YEARS
Age (Derived)	87
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	NEURONTIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1947
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1947
Start Year (derived)	1947
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	CATARACT RIGHT EYE
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	HYPERTRIGLUCYCEDEMIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	ARTHRITIS HANDS
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	ARTHRITIS LOWER BACK
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	SPINAL STENOSIS
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	SCOLIOSIS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	01 JAN 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 12:20
Height (xxx.x)	150.4 cm
Weight (xxx.x)	61.1 kg
BMI (xxx.x)	27.01130 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 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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Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 16:32:07

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Date of assessment (dd MMM yyyy) 29 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) 01 JAN 1987

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 16:32:08

Generated On: 10 Jun 2021 08:23:30

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 True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 16:32:08

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	29 AUG 2020

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

Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

What was the date of randomization? (dd MMM yyyy) 29 AUG 2020

What was the participant's randomization number? 189018

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 12:30
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 13:26
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

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) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

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) 29 AUG 2020

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 13:52

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) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	29 AUG 2020
Collection time (00:00-23:59)	13:20 (24 HR)
Collection date and time (derived)	29 AUG 2020 13:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:08	29 AUG 2020 13:08
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

98.3 °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

29 AUG 2020 14:34

PC Open Date & Time

29 AUG 2020 14:12

PC Close Date & Time

29 AUG 2020 16:42

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

98.6 °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	29 AUG 2020 20:29
PC Open Date & Time	29 AUG 2020 17:37
PC Close Date & Time	30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 16:12

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

98.7 °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

31 AUG 2020 16:27

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

01 SEP 2020 16:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

98.4 °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

02 SEP 2020 16:29

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

97.1 °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

03 SEP 2020 17:27

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

98.4 °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

04 SEP 2020 20:17

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

29 AUG 2020 14:35

PC Open Date & Time

29 AUG 2020 14:12

PC Close Date & Time

29 AUG 2020 16:42

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

29 AUG 2020 20:31

PC Open Date & Time

29 AUG 2020 17:37

PC Close Date & Time

30 AUG 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

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)**

1

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.**

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

30 AUG 2020 16:18

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

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)**

1

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.**

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

31 AUG 2020 16:29

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 16:59

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:30

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

03 SEP 2020 17:27

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

04 SEP 2020 20:17

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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 ☐

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 14:36
PC Open Date & Time	29 AUG 2020 14:12
PC Close Date & Time	29 AUG 2020 16:42

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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 ☐

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 20:31
PC Open Date & Time	29 AUG 2020 17:37
PC Close Date & Time	30 AUG 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

53 of 1733

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	30 AUG 2020 16:18
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 1733

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	31 AUG 2020 16:30
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 1733

EAB) (1725)

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	01 SEP 2020 17:00
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 1733

EAB) (1725)

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	02 SEP 2020 16:31
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

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 ☒

PRODUCTION RELEASE (v12.003

61 of 1733

EAB) (1725)

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	03 SEP 2020 17:28
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

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)

63 of 1733

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	04 SEP 2020 20:18
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	06 SEP 2020 13:04
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 8

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 and Time

05 SEP 2020 12:00

PC Close Date and Time

06 SEP 2020 11:59

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 9

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 06 SEP 2020 13:04

PC Open Date and Time 06 SEP 2020 12:00

PC Close Date and Time 07 SEP 2020 11:59

US3592247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3592247

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3592247

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3592247

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 10:45
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 12:08
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3592247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 2020

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

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

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) 26 SEP 2020

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 11:35

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

US3592247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	26 SEP 2020
Collection time (00:00-23:59)	11:04 (24 HR)
Collection date and time (derived)	26 SEP 2020 11:04

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Collection date (dd MMM yyyy)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	26 SEP 2020 11:05
Nasopharyngeal Swab 2	No		

US3592247

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:10

PC Open Date & Time

26 SEP 2020 11:55

PC Close Date & Time

26 SEP 2020 14:25

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

97.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp	27 SEP 2020 10:42
PC Open Date & Time	26 SEP 2020 15:20
PC Close Date & Time	27 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.7 °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

27 SEP 2020 20:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

98.7 °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

28 SEP 2020 19:29

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

29 SEP 2020 19:53

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

98.7 °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

30 SEP 2020 20:21

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

98.6 °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

01 OCT 2020 19:40

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

98.7 °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

02 OCT 2020 22:38

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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 ☐

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

1

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

26 SEP 2020 12:11

PC Open Date & Time

26 SEP 2020 11:55

PC Close Date & Time

26 SEP 2020 14:25

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

27 SEP 2020 08:50

PC Open Date & Time

26 SEP 2020 15:20

PC Close Date & Time

27 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 14:09

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 19:26

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 13:13

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 20:16

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

01 OCT 2020 19:28

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

02 OCT 2020 22:38

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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 ☐

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 12:12
PC Open Date & Time	26 SEP 2020 11:55
PC Close Date & Time	26 SEP 2020 14:25

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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 ☐

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

No ☒

Yes ☐

PC Time stamp	27 SEP 2020 08:51
PC Open Date & Time	26 SEP 2020 15:20
PC Close Date & Time	27 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

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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US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	27 SEP 2020 14:09
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

		Yes ☐
PC Time stamp	28 SEP 2020 19:24	
PC Open Date & Time	28 SEP 2020 12:00	
PC Close Date & Time	29 SEP 2020 11:59	

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	29 SEP 2020 13:13
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	30 SEP 2020 20:16
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	01 OCT 2020 19:29
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

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EAB) (1725)

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

Yes ☐	
PC Time stamp	02 OCT 2020 12:33
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3592247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3592247

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:32:07

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3592247

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3592247

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 14:10
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

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.

US3592247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	14:39 (24 HR)
Collection date and time (derived)	28 OCT 2020 14:39

US3592247

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:02:34

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 16:31:43
Patient Cloud Open Date & Time	29 OCT 2020 00:01
Patient Cloud Close Date & Time	02 NOV 2020 23:59

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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

05 NOV 2020 09:12:28

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	12 NOV 2020 07:29:55
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	19 NOV 2020 20:25:34
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 13:07:25
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 10:34:34
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 12:01:33

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 09:43:37
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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

21 DEC 2020 09:25:25

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 09:33:15
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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

04 JAN 2021 07:57:23

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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

13 JAN 2021 12:01:08

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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	18 JAN 2021 08:53:30
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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

25 JAN 2021 09:00:14

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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

01 FEB 2021 11:27:22

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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

08 FEB 2021 07:58:07

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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

18 FEB 2021 21:48:11

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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	24 FEB 2021 20:33:16
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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	03 MAR 2021 14:33:55
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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	08 MAR 2021 09:20:55
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3592247

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:23:30

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

US3592247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:59:38

Generated On: 10 Jun 2021 08:23:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592247

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:59:38

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3592247

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592247

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

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

US3592247

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592247

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:23:30

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3592247

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:23:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3592247

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

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3592247

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

Form: Unblinding

Generated On: 10 Jun 2021 08:23:30

Date of updated informed consent (<i>dd MMM yyyy</i>)		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
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 (<i>dd MMM yyyy</i>)		
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		

US3592247

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

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

US3592247

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:23:30

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00 - 23:59</i>)	_____
Collection Date and Time (derived)	_____

US3592247

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 15:57:00

Generated On: 10 Jun 2021 08:23:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

AEID	USA-US103-2020-MRNA-1273-P30 1000008
Adverse event	BRADYCARDIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	10 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 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	16 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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EAB) (1725)

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US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

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

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

SUBJECT CALLED ON
12NOV2020 TO REPORT BEING
HOSPITALIZED DUE TO
BRADYCARDIC HEART RATE
OF 43 AND VERTIGO. SHE ALSO
REPORTED ABDOMINAL PAIN
FOR ONE MONTH. SHE LIVES IN
A NURSING FACILITY. AT THE
TIME OF THE CALL SHE IS
BEING GIVEN ANTIBIOTICS,
POTASSIUM, AND PERCOCET
AND WILL HAVE A PICC LINE
PLACED. MEDICAL RECORDS
WILL BE OBTAINED FOR MORE
INFORMATION

FOLLOW UP #1: MEDICAL
RECORDS RECEIVED. SUBJECT
PRESENTED TO ED WITH
BRADYCARDIA AND
GENERALIZED
WEAKNESS/FATIGUE. SHE
REPORTED ABDOMINAL PAIN
X1 MONTH. CT SCAN WAS
OBTAINED AND REVEALED
FLUID
COLLECTION WITHIN VENTRAL
MESH ASSOCIATED WITH
VENTRAL HERNIA REPAIR
CONCERNING FOR INFECTED
MESH
MATERIAL WITH ABSCESS. A
PORTION OF THE BOWEL WAS
ALSO DISCOVERED TO BE
ADHERED TO ABDOMINAL

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

WALL.
SECONDARY TO MESH
INFECTION, CHOLELITHIASIS –
MILDLY DILATED COMMON
BILE DUCT AND
INTRAHEPATIC BILIARY
DUCTAL DILATATION WAS
NOTED. CHEST X-RAY SHOWED
NO EVIDENCE OF ACUTE
CARDIOPULMONARY
ABNORMALITY.
EKG ON 10NOV2020 SHOWED
SINUS BRADYCARDIA. EKG ON
11NOV2020 SHOWED ATRIAL
FIBRILLATION REPLACED
SINUS RHYTHM COMPARED TO
THE DAY BEFORE. A CT
GUIDED ABSCESS DRAINAGE
WAS COMPLETED ON
13NOV2020. APPROXIMATELY 5
CC'S OF PURULENT MATERIAL
WAS ASPIRATED AND A JP
DRAIN WAS PLACED FOR
CONTINUED DRAINAGE OF THE
ABSCESS. PATHOLOGY REPORT
NOT INCLUDED IN RECORDS
AT THIS TIME. SUBJECT WAS
GIVEN IV ANTIBIOTIC
ERTAPENEM FOR MESH
INFECTION AND STARTED ON
AMIODARONE 200MG BID FOR
ATRIAL
FIBRILLATION. SUBJECT WAS
DISCHARGED WITH DRAIN
AND REQUESTED

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

TO FOLLOW UP WITH
INFECTIOUS DISEASE
PHYSICIAN AND
CARDIOLOGIST AS WELL AS
ATTENDING PHYSICIAN.
POSSIBLY MORE RECORDS TO
COME.

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

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

AEID	
Adverse event	VERTIGO
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 15:56:58

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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 _____	
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 (3)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

AEID	
Adverse event	ABDOMINAL ABSCESS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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 (4)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

AEID	
Adverse event	HYPOKALEMIA
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

AEID	
Adverse event	SEASONAL ALLERGIES
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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 (6)

Data signed: (b) (4) 16 Apr 2021 15:56:58

Generated On: 10 Jun 2021 08:23:30

AEID	
Adverse event	CHOLELITHIASIS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 15:56:58

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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 _____	
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)	_____

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 15:57:03

Generated On: 10 Jun 2021 08:23:30

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication PROLIA

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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 6 MONTHS

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 (1)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 FEB 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication SPINAL STENOSIS

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication LOPID

Prophylaxis Yes ☐
No ☒

Indication HYPERTRIGLYCERIDEMIA

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 09:44:22

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication MAXIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 75/50

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) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2001	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication COREG

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS HAND

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 (6)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS HAND

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 ☐

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) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication ERTAPENEM

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL ABSCESS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐ No ☒	
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes ☐ No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒	

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication FEXOFENADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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 (11)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 22 NOV 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Name of Medication AUGMENTIN
(AMOXICILLIN/CLAVULANATE)

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL ABSCESS

Dose per administration 875/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

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

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 15:57:03

Generated On: 10 Jun 2021 08:23:30

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 15:57:03

Generated On: 10 Jun 2021 08:23:30

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 NOV 2020	CT GUIDED ABDOMINAL ABSCESS DRAINAGE	Adverse Event	
10 NOV 2020	ECHOCARDIOGRAM	Adverse Event	
11 NOV 2020	ECHOCARDIOGRAM	Adverse Event	
12 NOV 2020	ECHOCARDIOGRAM	Adverse Event	
10 NOV 2020	CT ABDOMEN/PELVIS	Adverse Event	
10 NOV 2020	CHEST X-RAY	Adverse Event	

US3592247

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

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

US3592247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

Date of study discontinuation/completion (dd MMM yyyy) 19 JAN 2021

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 RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY

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	☐

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

SAEID	USA-US103-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

SAEID	USA-US103-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/NOV/2020 14:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 09:44:22

Generated On: 10 Jun 2021 08:23:30

SAEID	USA-US103-2020-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	14/APR/2021 10:48
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

US3592247 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

US3592247

Form: Participant Creation

Generated On: 10 Jun 2021 08:23:30

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'US3592247'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 17:15:30

US3592247

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:37:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:47:14

US3592247

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:37:06
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 17:15:31

US3592247

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:37:06
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Aug 2020 20:47:14

US3592247

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'SCRN'	System	31 Aug 2020 20:47:14

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered (b) (6) 1933'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 17:15:32

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '87'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'YEARS'	System	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '87'	System	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered 'l'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:23:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:47:33

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:16
User entered '29 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Aug 2020'	System	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '2020'	System	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:16
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:35:03
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:16
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:16
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:16
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 19:00:37

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:16
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 17:15:31

US3592247

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:23:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'l'	System	29 Aug 2020 19:00:42

US3592247

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 19:00:42

US3592247

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:23:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:57:31

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 08:06:52
Data point term sent to Coder	System	31 Aug 2020 20:59:14
User entered 'neurontin allergy'	(b) (4), (b) (6)	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 2009'	(b) (4), (b) (6)	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 2009'	System	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '2009'	System	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:58:29

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:00:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:00:33
Data point term sent to Coder	System	31 Aug 2020 20:59:14
User entered 'myopia'	(b) (4), (b) (6)	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 1947'	(b) (4), (b) (6)	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 1947'	System	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '1947'	System	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:58:39

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:00:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:00:33
Data point term sent to Coder	System	31 Aug 2020 20:59:15
User entered 'cataract right eye'	(b) (4), (b) (6)	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 2010'	(b) (4), (b) (6)	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 2010'	System	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '2010'	System	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:59:07

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:00:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:00:34
Data point term sent to Coder	System	31 Aug 2020 21:00:16
User entered 'hypertension'	(b) (4), (b) (6)	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 1987'	(b) (4), (b) (6)	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 1987'	System	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '1987'	System	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:59:20

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated triglycerides, PT: Hypertriglyceridaemia, LLT: Hypertriglyceridaemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:12:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:12:47
Data point term sent to Coder	System	31 Aug 2020 21:00:16
User entered 'hypertriglyceridemia'	(b) (4), (b) (6)	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 2016'	(b) (4), (b) (6)	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (D) (4), (U) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(D) (4), (b) (6)	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 2016'	System	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '2016'	System	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 20:59:37

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:01:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:01:34
Data point term sent to Coder	System	31 Aug 2020 21:01:17
User entered 'osteoporosis'	(b) (4), (b) (6)	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 2019'	(b) (4), (b) (6)	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 2019'	System	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '2019'	System	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:00:17

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:42
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:31:14
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:49:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Hand arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:02:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:02:34
Data point term sent to Coder	System	31 Aug 2020 21:01:17
User entered 'arthritis hands'	(b) (4), (b) (6)	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'UN UNK 1995'	(b) (4), (b) (6)	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 1995'	System	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '1995'	System	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:00:30

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Spondyloarthropathies, PT: Spondylitis, LLT: Back arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:18:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:18:56
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:31:16
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:50:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:01:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:01:34
Data point term sent to Coder	System	31 Aug 2020 21:01:18
User entered 'ARTHRITIS lower back'	(b) (4), (b) (6)	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 1995'	(b) (4), (b) (6)	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 1995'	System	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '1995'	System	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:00:53

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:01:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:01:34
Data point term sent to Coder	System	31 Aug 2020 21:01:19
User entered 'spinal stenosis'	(b) (4), (b) (6)	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 2009'	(b) (4), (b) (6)	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 2009'	System	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '2009'	System	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:01:05

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Scoliosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:03:49
Data point term sent to Coder	System	31 Aug 2020 21:02:19
User entered 'scoliosis'	(b) (4), (b) (6)	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'un UNK 2019'	(b) (4), (b) (6)	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 2019'	System	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '2019'	System	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	31 Aug 2020 21:01:24

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
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) (b) (4)	07 Oct 2020 23:41:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 23:41:00
Data point term sent to Coder	System	07 Oct 2020 22:30:35
User entered 'POSTMENOPAUSAL'	(b) (4), (b) (6)	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '01 Jan 1987'	(b) (4), (b) (6)	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:42
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 18:58:00
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'Jan 1987'	System	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '1987'	System	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered empty.	System	07 Oct 2020 22:29:54

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:53
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:53
User entered '12:20'	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '29 Aug 2020 12:20'	System	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:53
User entered '150.4' cm	(b) (4), (b) (6)	31 Aug 2020 20:50:25
DataPoint set to visible.	System	29 Aug 2020 19:00:42

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:53
User entered '61.1' kg	(b) (4), (b) (6)	31 Aug 2020 20:50:25
DataPoint set to visible.	System	29 Aug 2020 19:00:42

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered '27.01130'	System	31 Aug 2020 20:50:25
DataPoint set to visible.	System	29 Aug 2020 19:00:42

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'kg/m2'	System	31 Aug 2020 20:50:25
DataPoint set to visible.	System	29 Aug 2020 19:00:42

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 00:26:57
User entered '98.6' F	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 00:26:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:53
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 00:26:57
User entered '69'	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'bpm'	System	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 00:26:57
User entered '16'	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'breaths/min'	System	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:50:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 00:26:57
User entered '119'	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'mmHg'	System	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 00:26:57
User entered '54'	(b) (4), (b) (6)	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User entered 'mmHg'	System	31 Aug 2020 20:50:25

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45

US3592247

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45

US3592247

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:23:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 20:29:17
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:50:38

US3592247

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:23:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:50:59
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 20:29:17
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:50:38

US3592247

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:23:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:03
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:51:21

US3592247

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:23:30

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:03
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	31 Aug 2020 20:51:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 20:51:29
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	31 Aug 2020 20:51:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:51:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:23:30

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:03
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:06:06
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'This has now been recorded on MH' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 22:36:16
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 12:23:20
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	31 Aug 2020 20:51:21

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Folder: Screening

Form: Childbearing Potential

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[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:03
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:51:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:03
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:51:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:23:30

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:03
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:51:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:03
User entered '01 Jan 1987'	(b) (4), (b) (6)	31 Aug 2020 20:51:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:23:30

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:03
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:51:21

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Folder: Screening

Form: Risk of Exposure

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[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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

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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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Form: Risk of Exposure

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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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Form: Risk of Exposure

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[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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Form: Risk of Exposure

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[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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

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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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

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[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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

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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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

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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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

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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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:23:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:53:29

US3592247

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered 'l'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

US3592247

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:23:30

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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

US3592247

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:23:30

[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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:23:30

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 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:51:15
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:53:29

US3592247

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:23:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:53:29

US3592247

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:23:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:14:45
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:15
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:53:29

US3592247

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:53:42

US3592247

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:25
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:53:42

US3592247

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Aug 2020 20:53:42

US3592247

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'VISIT1'	System	31 Aug 2020 20:53:42

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:39
User entered '29 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:45:36

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:39
User entered '189018'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:45:36

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:39
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:45:36

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

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)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:39
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:56:52

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

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)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:39
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:56:52

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:39
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:56:52

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:39
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:56:52

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:51:39
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:56:52

US3592247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:23:30

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 10:01:08
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'completed ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:47:01
User entered 'No (N)'	(b) (4), (b) (6)	30 Dec 2020 15:46:57
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 20:32:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:37:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:37:50

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:23:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:23:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:23:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:23:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '12:30'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '29 Aug 2020 12:30'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '69'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'bpm'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '16'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'breaths/min'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '119'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User closed query 'Per CDM: Diastolic BP is out of range. kindly specify CS or NCS. If CS, consider adding an AE' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 11:28:14
Query 'Per CDM: Diastolic BP is out of range. kindly specify CS or NCS. If CS, consider adding an AE' answered with 'Not clinically significant per investigator' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 22:32:37
User opened query 'Per CDM: Diastolic BP is out of range. kindly specify CS or NCS. If CS, consider adding an AE' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:01:20
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 07:01:00
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Confirm correct as entered.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 19:21:52
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:11:11
User entered '54'	(b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:23:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:23:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '13:26'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '29 Aug 2020 13:26'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '66'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'bpm'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '16'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'breaths/min'	System	31 Aug 2020 20:55:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '112'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '63'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	31 Aug 2020 20:55:18

US3592247

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:23:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:55:27

US3592247

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:23:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:55:27

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered '13:52'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '29 Aug 2020 13:52'	System	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'ONCE'	System	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 19:01:06

US3592247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:55:39

US3592247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:07
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:55:39

US3592247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:07
User entered '13:20'	(b) (4), (b) (6)	31 Aug 2020 20:55:39

US3592247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '29 Aug 2020 13:20'	System	31 Aug 2020 20:55:39

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:23:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:18
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:23:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:23:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:23:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:18
User entered '13:08'	(b) (4), (b) (6)	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:23:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '29 Aug 2020 13:08'	System	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:23:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:23:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:18
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:23:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:18
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:23:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered empty.	System	31 Aug 2020 20:55:51

US3592247

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:55:55

US3592247

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'I'	System	31 Aug 2020 20:55:55

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:33:42', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '28cf6eaf-9d26-47ca-aa1b-9e62090411ec' User entered 'Yes (Y)'	System	29 Aug 2020 19:34:28
	System	29 Aug 2020 19:34:28

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:33:51', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '28cf6eaf-9d26-47ca-aa1b-9e62090411ec' User entered '98.3'	System	29 Aug 2020 19:34:28
	System	29 Aug 2020 19:34:28

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:34:09', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '28cf6eaf-9d26-47ca-aa1b-9e62090411ec'	System	29 Aug 2020 19:34:28
User entered 'No (N)'	System	29 Aug 2020 19:34:28

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:34:25', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '28cf6eaf-9d26-47ca-aa1b-9e62090411ec' User entered '29 Aug 2020 14:34'	System	29 Aug 2020 19:34:28
	System	29 Aug 2020 19:34:28

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 14:12'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 16:42'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:28:50', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'f3143c83-6ffd-4d47-9ec0-5a11398f5d0e' User entered 'Yes (Y)'	System	30 Aug 2020 01:29:37
	System	30 Aug 2020 01:29:37

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:29:10', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'f3143c83-6ffd-4d47-9ec0-5a11398f5d0e' User entered '98.6'	System	30 Aug 2020 01:29:37
	System	30 Aug 2020 01:29:37

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:29:15', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'f3143c83-6ffd-4d47-9ec0-5a11398f5d0e'	System	30 Aug 2020 01:29:37
User entered 'No (N)'	System	30 Aug 2020 01:29:37

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:29:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'f3143c83-6ffd-4d47-9ec0-5a11398f5d0e' User entered '29 Aug 2020 20:29'	System	30 Aug 2020 01:29:37
	System	30 Aug 2020 01:29:37

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 17:37'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 2'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:12:05', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '48b78fc5-016a-46cf-9082-93dc71fd2d8a' User entered 'Yes (Y)'	System	30 Aug 2020 21:12:36
	System	30 Aug 2020 21:12:36

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:12:16', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '48b78fc5-016a-46cf-9082-93dc71fd2d8a' User entered '98.2'	System	30 Aug 2020 21:12:36
	System	30 Aug 2020 21:12:36

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:12:21', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '48b78fc5-016a-46cf-9082-93dc71fd2d8a'	System	30 Aug 2020 21:12:36
User entered 'No (N)'	System	30 Aug 2020 21:12:36

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:12:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '48b78fc5-016a-46cf-9082-93dc71fd2d8a' User entered '30 Aug 2020 16:12'	System	30 Aug 2020 21:12:36
	System	30 Aug 2020 21:12:36

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 3'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:27:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '809e3cad-8ad8-485d-ab08-1aea69d12195'	System	31 Aug 2020 21:27:36
User entered 'Yes (Y)'	System	31 Aug 2020 21:27:36

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:27:17', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '809e3cad-8ad8-485d-ab08-1aea69d12195' User entered '98.7'	System	31 Aug 2020 21:27:36
	System	31 Aug 2020 21:27:36

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:27:23', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '809e3cad-8ad8-485d-ab08-1aea69d12195'	System	31 Aug 2020 21:27:36
User entered 'No (N)'	System	31 Aug 2020 21:27:36

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:27:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '809e3cad-8ad8-485d-ab08-1aea69d12195' User entered '31 Aug 2020 16:27'	System	31 Aug 2020 21:27:36
	System	31 Aug 2020 21:27:36

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 4'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:57:46', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '0bd4e74b-db6d-4dba-b5d3-2fad7140e847' User entered 'Yes (Y)'	System	01 Sep 2020 21:58:11
	System	01 Sep 2020 21:58:11

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:57:59', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '0bd4e74b-db6d-4dba-b5d3-2fad7140e847' User entered '97.3'	System	01 Sep 2020 21:58:11
	System	01 Sep 2020 21:58:11

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:58:03', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '0bd4e74b-db6d-4dba-b5d3-2fad7140e847'	System	01 Sep 2020 21:58:11
User entered 'No (N)'	System	01 Sep 2020 21:58:11

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:58:09', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '0bd4e74b-db6d-4dba-b5d3-2fad7140e847' User entered '01 Sep 2020 16:58'	System	01 Sep 2020 21:58:11
	System	01 Sep 2020 21:58:11

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 5'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:29:28', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'fd88fbfe-641c-4080-be33-f6f6fd66f5b6'	System	02 Sep 2020 21:29:59
User entered 'Yes (Y)'	System	02 Sep 2020 21:29:59

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:29:41', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'fd88fbfe-641c-4080-be33-f6f6fd66f5b6' User entered '98.4'	System	02 Sep 2020 21:29:59
	System	02 Sep 2020 21:29:59

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:29:45', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'fd88fbfe-641c-4080-be33-f6f6fd66f5b6'	System	02 Sep 2020 21:29:59
User entered 'No (N)'	System	02 Sep 2020 21:29:59

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:29:54', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'fd88fbfe-641c-4080-be33-f6f6fd66f5b6' User entered '02 Sep 2020 16:29'	System	02 Sep 2020 21:29:59
	System	02 Sep 2020 21:29:59

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 6'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:26:56', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '529e57d1-9c46-4489-8e44-ac31e9e267bf' User entered 'Yes (Y)'	System	03 Sep 2020 22:27:18
	System	03 Sep 2020 22:27:18

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:05', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '529e57d1-9c46-4489-8e44-ac31e9e267bf' User entered '97.1'	System	03 Sep 2020 22:27:18
	System	03 Sep 2020 22:27:18

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '529e57d1-9c46-4489-8e44-ac31e9e267bf' User entered 'No (N)'	System	03 Sep 2020 22:27:18
	System	03 Sep 2020 22:27:18

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:16', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '529e57d1-9c46-4489-8e44-ac31e9e267bf' User entered '03 Sep 2020 17:27'	System	03 Sep 2020 22:27:18
	System	03 Sep 2020 22:27:18

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 7'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:16:48', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e6e54132-c11a-414e-81a7-31509e651463' User entered 'Yes (Y)'	System	05 Sep 2020 01:17:09
	System	05 Sep 2020 01:17:09

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:16:56', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e6e54132-c11a-414e-81a7-31509e651463' User entered '98.4'	System	05 Sep 2020 01:17:09
	System	05 Sep 2020 01:17:09

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e6e54132-c11a-414e-81a7-31509e651463' User entered 'No (N)'	System	05 Sep 2020 01:17:09
	System	05 Sep 2020 01:17:09

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:06', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e6e54132-c11a-414e-81a7-31509e651463' User entered '04 Sep 2020 20:17'	System	05 Sep 2020 01:17:09
	System	05 Sep 2020 01:17:09

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:35:03', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '987ec6be-d49b-4ea2-8618-6ad3a9461391' User entered 'None (1)'	System	29 Aug 2020 19:36:01
	System	29 Aug 2020 19:36:01

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:35:14', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '987ec6be-d49b-4ea2-8618-6ad3a9461391' User entered 'No (N)'	System	29 Aug 2020 19:36:01
	System	29 Aug 2020 19:36:01

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:35:26', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '987ec6be-d49b-4ea2-8618-6ad3a9461391' User entered 'No (N)'	System	29 Aug 2020 19:36:01
	System	29 Aug 2020 19:36:01

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:35:36', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '987ec6be-d49b-4ea2-8618-6ad3a9461391' User entered 'None (1)'	System	29 Aug 2020 19:36:01
	System	29 Aug 2020 19:36:01

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:35:58', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '987ec6be-d49b-4ea2-8618-6ad3a9461391' User entered '29 Aug 2020 14:35'	System	29 Aug 2020 19:36:01
	System	29 Aug 2020 19:36:01

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 14:12'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 16:42'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:31:17', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ce946ae5-ee46-497a-96c1-55d8d3ebc16f' User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 01:31:59
	System	30 Aug 2020 01:31:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:31:22', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ce946ae5-ee46-497a-96c1-55d8d3ebc16f' User entered 'No (N)'	System	30 Aug 2020 01:31:59
	System	30 Aug 2020 01:31:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:31:30', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ce946ae5-ee46-497a-96c1-55d8d3ebc16f' User entered 'No (N)'	System	30 Aug 2020 01:31:59
	System	30 Aug 2020 01:31:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:31:39', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ce946ae5-ee46-497a-96c1-55d8d3ebc16f' User entered 'None (1)'	System	30 Aug 2020 01:31:59
	System	30 Aug 2020 01:31:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:31:54', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ce946ae5-ee46-497a-96c1-55d8d3ebc16f' User entered '29 Aug 2020 20:31'	System	30 Aug 2020 01:31:59
	System	30 Aug 2020 01:31:59

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 17:37'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 2'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:15:03', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5ae7cd7-9ec9-4997-972d-8f921686fd2d'	System	30 Aug 2020 21:18:05
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 21:18:05

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:15:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5ae7cd7-9ec9-4997-972d-8f921686fd2d' User entered 'Yes (Y)'	System	30 Aug 2020 21:18:05
	System	30 Aug 2020 21:18:05

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:17:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5ae7cd7-9ec9-4997-972d-8f921686fd2d' User entered '1'	System	30 Aug 2020 21:18:05
	System	30 Aug 2020 21:18:05

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:16:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5ae7cd7-9ec9-4997-972d-8f921686fd2d' User entered 'No (N)'	System	30 Aug 2020 21:18:05
	System	30 Aug 2020 21:18:05

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:16:54', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5ae7cd7-9ec9-4997-972d-8f921686fd2d' User entered 'None (1)'	System	30 Aug 2020 21:18:05
	System	30 Aug 2020 21:18:05

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:01', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5ae7cd7-9ec9-4997-972d-8f921686fd2d' User entered '30 Aug 2020 16:18'	System	30 Aug 2020 21:18:05
	System	30 Aug 2020 21:18:05

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 3'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:27:45', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd79b8c8a-96d0-4c9b-a09e-1ce5cec043b3'	System	31 Aug 2020 21:29:21
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 21:29:21

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:28:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd79b8c8a-96d0-4c9b-a09e-1ce5cec043b3' User entered 'Yes (Y)'	System	31 Aug 2020 21:29:21
	System	31 Aug 2020 21:29:21

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:28:44', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd79b8c8a-96d0-4c9b-a09e-1ce5cec043b3' User entered '1'	System	31 Aug 2020 21:29:21
	System	31 Aug 2020 21:29:21

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:28:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd79b8c8a-96d0-4c9b-a09e-1ce5cec043b3' User entered 'No (N)'	System	31 Aug 2020 21:29:21
	System	31 Aug 2020 21:29:21

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:04', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd79b8c8a-96d0-4c9b-a09e-1ce5cec043b3'	System	31 Aug 2020 21:29:21
User entered 'None (1)'	System	31 Aug 2020 21:29:21

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:20', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd79b8c8a-96d0-4c9b-a09e-1ce5cec043b3' User entered '31 Aug 2020 16:29'	System	31 Aug 2020 21:29:21
	System	31 Aug 2020 21:29:21

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 4'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:59:19', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '1d79d074-87a3-4f03-88f2-df949eef2d3a'	System	01 Sep 2020 21:59:54
User entered 'None (1)'	System	01 Sep 2020 21:59:54

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:59:23', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '1d79d074-87a3-4f03-88f2-df949eef2d3a' User entered 'No (N)'	System	01 Sep 2020 21:59:54
	System	01 Sep 2020 21:59:54

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:59:30', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '1d79d074-87a3-4f03-88f2-df949eef2d3a' User entered 'No (N)'	System	01 Sep 2020 21:59:54
	System	01 Sep 2020 21:59:54

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:59:41', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '1d79d074-87a3-4f03-88f2-df949eef2d3a'	System	01 Sep 2020 21:59:54
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 21:59:54

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:59:51', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '1d79d074-87a3-4f03-88f2-df949eef2d3a'	System	01 Sep 2020 21:59:54
User entered '01 Sep 2020 16:59'	System	01 Sep 2020 21:59:54

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 5'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:12', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dffe16a9-404a-4d7a-b149-e49c71ffdec3'	System	02 Sep 2020 21:30:33
User entered 'None (1)'	System	02 Sep 2020 21:30:33

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:15', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dffe16a9-404a-4d7a-b149-e49c71ffdec3' User entered 'No (N)'	System	02 Sep 2020 21:30:33
	System	02 Sep 2020 21:30:33

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:18', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dffe16a9-404a-4d7a-b149-e49c71ffdec3' User entered 'No (N)'	System	02 Sep 2020 21:30:33
	System	02 Sep 2020 21:30:33

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:24', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dffe16a9-404a-4d7a-b149-e49c71ffdec3'	System	02 Sep 2020 21:30:33
User entered 'None (1)'	System	02 Sep 2020 21:30:33

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:31', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dffe16a9-404a-4d7a-b149-e49c71ffdec3' User entered '02 Sep 2020 16:30'	System	02 Sep 2020 21:30:33
	System	02 Sep 2020 21:30:33

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 6'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:22', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9112590f-cb25-44b6-b7d7-68e516a82cf7'	System	03 Sep 2020 22:27:47
User entered 'None (1)'	System	03 Sep 2020 22:27:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:28', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9112590f-cb25-44b6-b7d7-68e516a82cf7'	System	03 Sep 2020 22:27:47
User entered 'No (N)'	System	03 Sep 2020 22:27:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9112590f-cb25-44b6-b7d7-68e516a82cf7' User entered 'No (N)'	System	03 Sep 2020 22:27:47
	System	03 Sep 2020 22:27:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:38', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9112590f-cb25-44b6-b7d7-68e516a82cf7'	System	03 Sep 2020 22:27:47
User entered 'None (1)'	System	03 Sep 2020 22:27:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:44', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9112590f-cb25-44b6-b7d7-68e516a82cf7' User entered '03 Sep 2020 17:27'	System	03 Sep 2020 22:27:47
	System	03 Sep 2020 22:27:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 7'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:13', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd05aa7bd-865c-4828-b8fc-8993b39f2f66'	System	05 Sep 2020 01:17:47
User entered 'None (1)'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:17', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd05aa7bd-865c-4828-b8fc-8993b39f2f66'	System	05 Sep 2020 01:17:47
User entered 'No (N)'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:20', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd05aa7bd-865c-4828-b8fc-8993b39f2f66'	System	05 Sep 2020 01:17:47
User entered 'No (N)'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:35', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd05aa7bd-865c-4828-b8fc-8993b39f2f66'	System	05 Sep 2020 01:17:47
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:44', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd05aa7bd-865c-4828-b8fc-8993b39f2f66'	System	05 Sep 2020 01:17:47
User entered '04 Sep 2020 20:17'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:36:09', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e4447050-37da-4ee3-a397-cb8a5e8f8a9b' User entered 'None (0)'	System	29 Aug 2020 19:36:59
	System	29 Aug 2020 19:36:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:36:14', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e4447050-37da-4ee3-a397-cb8a5e8f8a9b' User entered 'None (0)'	System	29 Aug 2020 19:36:59
	System	29 Aug 2020 19:36:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:36:22', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e4447050-37da-4ee3-a397-cb8a5e8f8a9b' User entered 'None (0)'	System	29 Aug 2020 19:36:59
	System	29 Aug 2020 19:36:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:36:25', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e4447050-37da-4ee3-a397-cb8a5e8f8a9b' User entered 'None (0)'	System	29 Aug 2020 19:36:59
	System	29 Aug 2020 19:36:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:36:28', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e4447050-37da-4ee3-a397-cb8a5e8f8a9b' User entered 'None (0)'	System	29 Aug 2020 19:36:59
	System	29 Aug 2020 19:36:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:36:32', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e4447050-37da-4ee3-a397-cb8a5e8f8a9b' User entered 'None (0)'	System	29 Aug 2020 19:36:59
	System	29 Aug 2020 19:36:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:36:42', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e4447050-37da-4ee3-a397-cb8a5e8f8a9b' User entered 'No (N)'	System	29 Aug 2020 19:36:59
	System	29 Aug 2020 19:36:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T14:36:53', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e4447050-37da-4ee3-a397-cb8a5e8f8a9b' User entered '29 Aug 2020 14:36'	System	29 Aug 2020 19:36:59
	System	29 Aug 2020 19:36:59

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 14:12'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 16:42'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:30:02', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '50d025e7-c500-4bb7-853d-7740a5ef0d00' User entered 'None (0)'	System	30 Aug 2020 01:31:06
	System	30 Aug 2020 01:31:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:30:05', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '50d025e7-c500-4bb7-853d-7740a5ef0d00' User entered 'None (0)'	System	30 Aug 2020 01:31:06
	System	30 Aug 2020 01:31:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:30:10', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '50d025e7-c500-4bb7-853d-7740a5ef0d00' User entered 'None (0)'	System	30 Aug 2020 01:31:06
	System	30 Aug 2020 01:31:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:30:14', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '50d025e7-c500-4bb7-853d-7740a5ef0d00' User entered 'None (0)'	System	30 Aug 2020 01:31:06
	System	30 Aug 2020 01:31:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:30:17', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '50d025e7-c500-4bb7-853d-7740a5ef0d00' User entered 'None (0)'	System	30 Aug 2020 01:31:06
	System	30 Aug 2020 01:31:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:30:20', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '50d025e7-c500-4bb7-853d-7740a5ef0d00' User entered 'None (0)'	System	30 Aug 2020 01:31:06
	System	30 Aug 2020 01:31:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:30:23', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '50d025e7-c500-4bb7-853d-7740a5ef0d00'	System	30 Aug 2020 01:31:06
User entered 'No (N)'	System	30 Aug 2020 01:31:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-29T20:31:04', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '50d025e7-c500-4bb7-853d-7740a5ef0d00' User entered '29 Aug 2020 20:31'	System	30 Aug 2020 01:31:06
	System	30 Aug 2020 01:31:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Aug 2020 17:37'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 2'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '61d0ebbb-0852-41b6-8008-1b1baa9aacf7' User entered 'None (0)'	System	30 Aug 2020 21:18:56
	System	30 Aug 2020 21:18:56

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:12', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '61d0ebbb-0852-41b6-8008-1b1baa9aacf7' User entered 'None (0)'	System	30 Aug 2020 21:18:56
	System	30 Aug 2020 21:18:56

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:15', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '61d0ebbb-0852-41b6-8008-1b1baa9aacf7' User entered 'None (0)'	System	30 Aug 2020 21:18:56
	System	30 Aug 2020 21:18:56

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:18', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '61d0ebbb-0852-41b6-8008-1b1baa9aacf7' User entered 'None (0)'	System	30 Aug 2020 21:18:56
	System	30 Aug 2020 21:18:56

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:21', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '61d0ebbb-0852-41b6-8008-1b1baa9aacf7' User entered 'None (0)'	System	30 Aug 2020 21:18:56
	System	30 Aug 2020 21:18:56

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:24', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '61d0ebbb-0852-41b6-8008-1b1baa9aecf7' User entered 'None (0)'	System	30 Aug 2020 21:18:56
	System	30 Aug 2020 21:18:56

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:29', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '61d0ebbb-0852-41b6-8008-1b1baa9aacf7' User entered 'No (N)'	System	30 Aug 2020 21:18:56
	System	30 Aug 2020 21:18:56

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-30T16:18:53', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '61d0ebbb-0852-41b6-8008-1b1baa9aecf7' User entered '30 Aug 2020 16:18'	System	30 Aug 2020 21:18:56
	System	30 Aug 2020 21:18:56

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 3'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:26', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '92fee342-d8cb-451a-af5e-284804e1c4d8'	System	31 Aug 2020 21:30:13
User entered 'None (0)'	System	31 Aug 2020 21:30:13

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:32', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '92fee342-d8cb-451a-af5e-284804e1c4d8'	System	31 Aug 2020 21:30:13
User entered 'No interference with activity (1)'	System	31 Aug 2020 21:30:13

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:36', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '92fee342-d8cb-451a-af5e-284804e1c4d8' User entered 'None (0)'	System	31 Aug 2020 21:30:13
	System	31 Aug 2020 21:30:13

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:40', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '92fee342-d8cb-451a-af5e-284804e1c4d8' User entered 'None (0)'	System	31 Aug 2020 21:30:13
	System	31 Aug 2020 21:30:13

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '92fee342-d8cb-451a-af5e-284804e1c4d8' User entered 'None (0)'	System	31 Aug 2020 21:30:13
	System	31 Aug 2020 21:30:13

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:46', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '92fee342-d8cb-451a-af5e-284804e1c4d8' User entered 'None (0)'	System	31 Aug 2020 21:30:13
	System	31 Aug 2020 21:30:13

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:29:50', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '92fee342-d8cb-451a-af5e-284804e1c4d8'	System	31 Aug 2020 21:30:13
User entered 'No (N)'	System	31 Aug 2020 21:30:13

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-08-31T16:30:11', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '92fee342-d8cb-451a-af5e-284804e1c4d8'	System	31 Aug 2020 21:30:13
User entered '31 Aug 2020 16:30'	System	31 Aug 2020 21:30:13

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 4'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T16:59:58', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '31b1cb08-641d-4c51-879a-29ac1e425037' User entered 'None (0)'	System	01 Sep 2020 22:00:39
	System	01 Sep 2020 22:00:39

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T17:00:02', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '31b1cb08-641d-4c51-879a-29ac1e425037'	System	01 Sep 2020 22:00:39
User entered 'No interference with activity (1)'	System	01 Sep 2020 22:00:39

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T17:00:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '31b1cb08-641d-4c51-879a-29ac1e425037' User entered 'None (0)'	System	01 Sep 2020 22:00:39
	System	01 Sep 2020 22:00:39

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T17:00:11', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '31b1cb08-641d-4c51-879a-29ac1e425037' User entered 'None (0)'	System	01 Sep 2020 22:00:39
	System	01 Sep 2020 22:00:39

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T17:00:14', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '31b1cb08-641d-4c51-879a-29ac1e425037' User entered 'None (0)'	System	01 Sep 2020 22:00:39
	System	01 Sep 2020 22:00:39

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T17:00:17', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '31b1cb08-641d-4c51-879a-29ac1e425037' User entered 'None (0)'	System	01 Sep 2020 22:00:39
	System	01 Sep 2020 22:00:39

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T17:00:22', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '31b1cb08-641d-4c51-879a-29ac1e425037' User entered 'No (N)'	System	01 Sep 2020 22:00:39
	System	01 Sep 2020 22:00:39

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-01T17:00:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '31b1cb08-641d-4c51-879a-29ac1e425037' User entered '01 Sep 2020 17:00'	System	01 Sep 2020 22:00:39
	System	01 Sep 2020 22:00:39

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 5'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:37', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '6b36704e-dc66-42e0-b563-ac8b728fdafe' User entered 'None (0)'	System	02 Sep 2020 21:31:11
	System	02 Sep 2020 21:31:11

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:40', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '6b36704e-dc66-42e0-b563-ac8b728fdafe' User entered 'None (0)'	System	02 Sep 2020 21:31:11
	System	02 Sep 2020 21:31:11

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '6b36704e-dc66-42e0-b563-ac8b728fdafe' User entered 'None (0)'	System	02 Sep 2020 21:31:11
	System	02 Sep 2020 21:31:11

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:46', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '6b36704e-dc66-42e0-b563-ac8b728fdafe' User entered 'None (0)'	System	02 Sep 2020 21:31:11
	System	02 Sep 2020 21:31:11

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '6b36704e-dc66-42e0-b563-ac8b728fdafe' User entered 'None (0)'	System	02 Sep 2020 21:31:11
	System	02 Sep 2020 21:31:11

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:53', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '6b36704e-dc66-42e0-b563-ac8b728fdafe' User entered 'None (0)'	System	02 Sep 2020 21:31:11
	System	02 Sep 2020 21:31:11

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:30:57', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '6b36704e-dc66-42e0-b563-ac8b728fdafe' User entered 'No (N)'	System	02 Sep 2020 21:31:11
	System	02 Sep 2020 21:31:11

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-02T16:31:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '6b36704e-dc66-42e0-b563-ac8b728fdafe' User entered '02 Sep 2020 16:31'	System	02 Sep 2020 21:31:11
	System	02 Sep 2020 21:31:11

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 6'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:50', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a764d3c-c976-41f8-ae7c-9a66454bf1a9' User entered 'None (0)'	System	03 Sep 2020 22:28:21
	System	03 Sep 2020 22:28:21

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:27:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a764d3c-c976-41f8-ae7c-9a66454bf1a9' User entered 'None (0)'	System	03 Sep 2020 22:28:21
	System	03 Sep 2020 22:28:21

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:28:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a764d3c-c976-41f8-ac7c-9a66454bf1a9' User entered 'None (0)'	System	03 Sep 2020 22:28:21
	System	03 Sep 2020 22:28:21

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:28:03', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a764d3c-c976-41f8-ac7c-9a66454bf1a9' User entered 'None (0)'	System	03 Sep 2020 22:28:21
	System	03 Sep 2020 22:28:21

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:28:06', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a764d3c-c976-41f8-ac7c-9a66454bfla9' User entered 'None (0)'	System	03 Sep 2020 22:28:21
	System	03 Sep 2020 22:28:21

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:28:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a764d3c-c976-41f8-ac7c-9a66454bf1a9' User entered 'None (0)'	System	03 Sep 2020 22:28:21
	System	03 Sep 2020 22:28:21

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:28:12', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a764d3c-c976-41f8-ac7c-9a66454bf1a9' User entered 'No (N)'	System	03 Sep 2020 22:28:21
	System	03 Sep 2020 22:28:21

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-03T17:28:19', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a764d3c-c976-41f8-ae7c-9a66454bf1a9' User entered '03 Sep 2020 17:28'	System	03 Sep 2020 22:28:21
	System	03 Sep 2020 22:28:21

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 7'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:50', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae391d22-b410-434d-90fc-737b9b979861' User entered 'None (0)'	System	05 Sep 2020 01:18:26
	System	05 Sep 2020 01:18:26

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae391d22-b410-434d-90fc-737b9b979861' User entered 'None (0)'	System	05 Sep 2020 01:18:26
	System	05 Sep 2020 01:18:26

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:17:59', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae391d22-b410-434d-90fc-737b9b979861' User entered 'None (0)'	System	05 Sep 2020 01:18:26
	System	05 Sep 2020 01:18:26

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:18:05', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae391d22-b410-434d-90fc-737b9b979861' User entered 'None (0)'	System	05 Sep 2020 01:18:26
	System	05 Sep 2020 01:18:26

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:18:09', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae391d22-b410-434d-90fc-737b9b979861' User entered 'None (0)'	System	05 Sep 2020 01:18:26
	System	05 Sep 2020 01:18:26

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:18:12', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae391d22-b410-434d-90fc-737b9b979861' User entered 'None (0)'	System	05 Sep 2020 01:18:26
	System	05 Sep 2020 01:18:26

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:18:16', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae391d22-b410-434d-90fc-737b9b979861' User entered 'No (N)'	System	05 Sep 2020 01:18:26
	System	05 Sep 2020 01:18:26

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-04T20:18:25', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae391d22-b410-434d-90fc-737b9b979861' User entered '04 Sep 2020 20:18'	System	05 Sep 2020 01:18:26
	System	05 Sep 2020 01:18:26

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	05 Sep 2020 01:17:47
User entered 'Day 9'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-06T13:04:30', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e7f2b493-25c1-46df-b1d0-f08e7ccc748e' User entered 'No (N)'	System	06 Sep 2020 18:04:37
	System	06 Sep 2020 18:04:37

US3592247

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-06T13:04:35', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e7f2b493-25c1-46df-b1d0-f08e7ccc748e' User entered '06 Sep 2020 13:04'	System	06 Sep 2020 18:04:37
	System	06 Sep 2020 18:04:37

US3592247

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	05 Sep 2020 01:17:47
User entered 'Day 8'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '05 Sep 2020 12:00'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	05 Sep 2020 01:17:47
User entered 'Day 9'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-06T13:04:45', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd1d23ec1-0817-486f-8234-af6fa068b116'	System	06 Sep 2020 18:04:51
User entered 'None (1)'	System	06 Sep 2020 18:04:51

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-06T13:04:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd1d23ec1-0817-486f-8234-af6fa068b116' User entered '06 Sep 2020 13:04'	System	06 Sep 2020 18:04:51
	System	06 Sep 2020 18:04:51

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 01:17:47

US3592247

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 01:17:47

US3592247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:54:09

US3592247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:52:33
User entered '5 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 19:54:09

US3592247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Sep 2020 19:54:09

US3592247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:33
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 19:54:09

US3592247

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 19:54:34

US3592247

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'l'	System	12 Sep 2020 19:54:34

US3592247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 20:30:05

US3592247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:45
User entered '13 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 20:30:05

US3592247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 20:30:05

US3592247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:52:45
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:30:05

US3592247

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:52:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:18:32

US3592247

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'l'	System	22 Sep 2020 14:18:32

US3592247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:18:52

US3592247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4)	13 Nov 2020 17:53:00
User entered '20 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 14:18:52

US3592247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 14:18:52

US3592247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4) (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:53:00
User entered empty.		22 Sep 2020 14:18:52

US3592247

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:53:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:19:25

US3592247

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'l'	System	22 Sep 2020 14:19:25

US3592247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:11:58

US3592247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:53:14
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:11:58

US3592247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:14
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Sep 2020 19:11:58

US3592247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'VISIT2'	System	26 Sep 2020 19:11:58

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:53:44
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '10:45'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '26 Sep 2020 10:45'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '98.8' F	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (u) (4), (u) (6)	13 Nov 2020 17:53:44
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '65'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'bpm'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '16'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'breaths/min'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '104'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User closed query 'Per CDM Please confirm value is CS or NCS.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:27:52
Query 'Per CDM Please confirm value is CS or NCS.' answered with 'not clinically significant ' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 16:19:15
User opened query 'Per CDM Please confirm value is CS or NCS.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:02:08
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 04:01:40
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Correct as entered' (Site from System).	(b) (4), (b) (6)	26 Sep 2020 19:16:11
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		26 Sep 2020 19:13:19
User entered '57'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:53:44
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '12:08'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '26 Sep 2020 12:08'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '98.2' F	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '54'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'bpm'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '16'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'breaths/min'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '108'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:44
User entered '61'	(b) (4), (b) (6)	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	26 Sep 2020 19:13:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:23:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:53:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:16:33

US3592247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:23:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:53:52
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:16:33

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:05
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:54:05
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:54:05
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:05
User entered '11:35'	(b) (4), (b) (6)	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '26 Sep 2020 11:35'	System	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:05
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:54:05
User entered 'ONCE'	System	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:23:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 16:38:34

US3592247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:16:55

US3592247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:54:11
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:16:55

US3592247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:11
User entered '11:04'	(b) (4), (b) (6)	26 Sep 2020 19:16:55

US3592247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '26 Sep 2020 11:04'	System	26 Sep 2020 19:16:55

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:23:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:54:24
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:23:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:23:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:23:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:24
User entered '11:05'	(b) (4), (b) (6)	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:23:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '26 Sep 2020 11:05'	System	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:23:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:23:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:24
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:23:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:24
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:23:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered empty.	System	26 Sep 2020 19:17:07

US3592247

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 19:17:19

US3592247

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'I'	System	26 Sep 2020 19:17:19

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:09:57', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'f902cdbe-a174-4b75-932d-57d3e5582e6d' User entered 'Yes (Y)'	System	26 Sep 2020 17:10:25
	System	26 Sep 2020 17:10:25

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:10:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'f902cdbe-a174-4b75-932d-57d3e5582e6d' User entered '98.2'	System	26 Sep 2020 17:10:25
	System	26 Sep 2020 17:10:25

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:10:14', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'f902cdbe-a174-4b75-932d-57d3e5582e6d' User entered 'No (N)'	System	26 Sep 2020 17:10:25
	System	26 Sep 2020 17:10:25

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:10:20', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'f902cdbe-a174-4b75-932d-57d3e5582e6d' User entered '26 Sep 2020 12:10'	System	26 Sep 2020 17:10:25
	System	26 Sep 2020 17:10:25

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 11:55'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 14:25'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T10:41:54', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5a61450-5832-4070-abc2-4c143ef79681' User entered 'Yes (Y)'	System	27 Sep 2020 15:42:30
	System	27 Sep 2020 15:42:30

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T10:42:12', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5a61450-5832-4070-abc2-4c143ef79681' User entered '97.4'	System	27 Sep 2020 15:42:30
	System	27 Sep 2020 15:42:30

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T10:42:21', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5a61450-5832-4070-abc2-4c143ef79681' User entered 'No (N)'	System	27 Sep 2020 15:42:30
	System	27 Sep 2020 15:42:30

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T10:42:25', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'c5a61450-5832-4070-abc2-4c143ef79681' User entered '27 Sep 2020 10:42'	System	27 Sep 2020 15:42:30
	System	27 Sep 2020 15:42:30

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 15:20'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 2'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T20:34:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '90486908-053e-42e2-a261-de02517c0de5' User entered 'Yes (Y)'	System	28 Sep 2020 01:35:14
	System	28 Sep 2020 01:35:14

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T20:34:52', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '90486908-053e-42e2-a261-de02517c0de5' User entered '99.7'	System	28 Sep 2020 01:35:14
	System	28 Sep 2020 01:35:14

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T20:34:59', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '90486908-053e-42e2-a261-de02517c0de5' User entered 'No (N)'	System	28 Sep 2020 01:35:14
	System	28 Sep 2020 01:35:14

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T20:35:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '90486908-053e-42e2-a261-de02517c0de5' User entered '27 Sep 2020 20:35'	System	28 Sep 2020 01:35:14
	System	28 Sep 2020 01:35:14

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 3'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:29:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9cdf012d-da7c-4778-804c-134ff4e3941a' User entered 'Yes (Y)'	System	29 Sep 2020 00:29:46
	System	29 Sep 2020 00:29:46

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:29:20', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9cdf012d-da7c-4778-804c-134ff4e3941a' User entered '98.7'	System	29 Sep 2020 00:29:46
	System	29 Sep 2020 00:29:46

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:29:27', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9cdf012d-da7c-4778-804c-134ff4e3941a' User entered 'No (N)'	System	29 Sep 2020 00:29:46
	System	29 Sep 2020 00:29:46

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:29:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '9cdf012d-da7c-4778-804c-134ff4e3941a' User entered '28 Sep 2020 19:29'	System	29 Sep 2020 00:29:46
	System	29 Sep 2020 00:29:46

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 4'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T19:53:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '38f288ac-7578-4a77-8902-3ab39fae1fe3' User entered 'Yes (Y)'	System	30 Sep 2020 00:53:37
	System	30 Sep 2020 00:53:37

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T19:53:22', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '38f288ac-7578-4a77-8902-3ab39fae1fe3' User entered '97.7'	System	30 Sep 2020 00:53:37
	System	30 Sep 2020 00:53:37

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T19:53:28', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '38f288ac-7578-4a77-8902-3ab39fae1fe3' User entered 'No (N)'	System	30 Sep 2020 00:53:37
	System	30 Sep 2020 00:53:37

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T19:53:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '38f288ac-7578-4a77-8902-3ab39fae1fe3' User entered '29 Sep 2020 19:53'	System	30 Sep 2020 00:53:37
	System	30 Sep 2020 00:53:37

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 5'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:20:40', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'fecd8818-4236-41a0-84b8-2b69beb20c72'	System	01 Oct 2020 01:21:17
User entered 'Yes (Y)'	System	01 Oct 2020 01:21:17

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:20:47', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'fecd8818-4236-41a0-84b8-2b69beb20c72' User entered '98.7'	System	01 Oct 2020 01:21:17
	System	01 Oct 2020 01:21:17

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:21:07', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'fecd8818-4236-41a0-84b8-2b69beb20c72'	System	01 Oct 2020 01:21:17
User entered 'No (N)'	System	01 Oct 2020 01:21:17

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:21:12', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'fec8818-4236-41a0-84b8-2b69beb20c72'	System	01 Oct 2020 01:21:17
User entered '30 Sep 2020 20:21'	System	01 Oct 2020 01:21:17

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 6'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:40:19', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '907e5763-5ef4-49d6-b203-2dc526d6ffa0' User entered 'Yes (Y)'	System	02 Oct 2020 00:40:43
	System	02 Oct 2020 00:40:43

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:40:29', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '907e5763-5ef4-49d6-b203-2dc526d6ffa0' User entered '98.6'	System	02 Oct 2020 00:40:43
	System	02 Oct 2020 00:40:43

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:40:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '907e5763-5ef4-49d6-b203-2dc526d6ffa0'	System	02 Oct 2020 00:40:43
User entered 'No (N)'	System	02 Oct 2020 00:40:43

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:40:40', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '907e5763-5ef4-49d6-b203-2dc526d6ffa0' User entered '01 Oct 2020 19:40'	System	02 Oct 2020 00:40:43
	System	02 Oct 2020 00:40:43

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 7'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:37:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a776578f-ac69-4640-9c2a-43eb047b996f' User entered 'Yes (Y)'	System	03 Oct 2020 03:38:16
	System	03 Oct 2020 03:38:16

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:38:04', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a776578f-ac69-4640-9c2a-43eb047b996f' User entered '98.7'	System	03 Oct 2020 03:38:16
	System	03 Oct 2020 03:38:16

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:38:09', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a776578f-ac69-4640-9c2a-43eb047b996f' User entered 'No (N)'	System	03 Oct 2020 03:38:16
	System	03 Oct 2020 03:38:16

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:38:13', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a776578f-ac69-4640-9c2a-43eb047b996f' User entered '02 Oct 2020 22:38'	System	03 Oct 2020 03:38:16
	System	03 Oct 2020 03:38:16

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:10:31', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd83fba87-29bf-4c27-af5d-07a860057f2b' User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 17:11:48
	System	26 Sep 2020 17:11:48

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:10:36', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd83fba87-29bf-4c27-af5d-07a860057f2b' User entered 'Yes (Y)'	System	26 Sep 2020 17:11:48
	System	26 Sep 2020 17:11:48

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:11:17', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd83fba87-29bf-4c27-af5d-07a860057f2b' User entered '1'	System	26 Sep 2020 17:11:48
	System	26 Sep 2020 17:11:48

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:11:30', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd83fba87-29bf-4c27-af5d-07a860057f2b'	System	26 Sep 2020 17:11:48
User entered 'No (N)'	System	26 Sep 2020 17:11:48

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:11:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd83fba87-29bf-4c27-af5d-07a860057f2b'	System	26 Sep 2020 17:11:48
User entered 'None (1)'	System	26 Sep 2020 17:11:48

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:11:42', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd83fba87-29bf-4c27-af5d-07a860057f2b' User entered '26 Sep 2020 12:11'	System	26 Sep 2020 17:11:48
	System	26 Sep 2020 17:11:48

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 11:55'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 14:25'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:49:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d37930-727c-4bf9-b920-7698162c92b2'	System	27 Sep 2020 13:50:24
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 13:50:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:49:59', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d37930-727c-4bf9-b920-7698162c92b2' User entered 'No (N)'	System	27 Sep 2020 13:50:24
	System	27 Sep 2020 13:50:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:07', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d37930-727c-4bf9-b920-7698162c92b2' User entered 'No (N)'	System	27 Sep 2020 13:50:24
	System	27 Sep 2020 13:50:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:14', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d37930-727c-4bf9-b920-7698162c92b2' User entered 'None (1)'	System	27 Sep 2020 13:50:24
	System	27 Sep 2020 13:50:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:21', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d37930-727c-4bf9-b920-7698162c92b2' User entered '27 Sep 2020 08:50'	System	27 Sep 2020 13:50:24
	System	27 Sep 2020 13:50:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 15:20'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 2'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:08:52', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd02c3e2a-72cc-45af-a27e-3720316ee84b'	System	27 Sep 2020 19:09:09
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 19:09:09

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:08:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd02c3e2a-72cc-45af-a27e-3720316ee84b' User entered 'No (N)'	System	27 Sep 2020 19:09:09
	System	27 Sep 2020 19:09:09

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:08:58', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd02c3e2a-72cc-45af-a27e-3720316ee84b' User entered 'No (N)'	System	27 Sep 2020 19:09:09
	System	27 Sep 2020 19:09:09

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:02', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd02c3e2a-72cc-45af-a27e-3720316ee84b'	System	27 Sep 2020 19:09:09
User entered 'None (1)'	System	27 Sep 2020 19:09:09

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd02c3e2a-72cc-45af-a27e-3720316ee84b' User entered '27 Sep 2020 14:09'	System	27 Sep 2020 19:09:09
	System	27 Sep 2020 19:09:09

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 3'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:25:13', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '20dbbf17-a14f-4f45-80a2-8cd193e8b86d'	System	29 Sep 2020 00:26:03
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 00:26:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:25:20', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '20dbbf17-a14f-4f45-80a2-8cd193e8b86d' User entered 'No (N)'	System	29 Sep 2020 00:26:03
	System	29 Sep 2020 00:26:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:25:26', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '20dbbf17-a14f-4f45-80a2-8cd193e8b86d' User entered 'No (N)'	System	29 Sep 2020 00:26:03
	System	29 Sep 2020 00:26:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:25:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '20dbbf17-a14f-4f45-80a2-8cd193e8b86d'	System	29 Sep 2020 00:26:03
User entered 'None (1)'	System	29 Sep 2020 00:26:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:26:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '20dbbf17-a14f-4f45-80a2-8cd193e8b86d' User entered '28 Sep 2020 19:26'	System	29 Sep 2020 00:26:03
	System	29 Sep 2020 00:26:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 4'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:13:24', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae8e7123-00c0-458f-a90d-494845a99236'	System	29 Sep 2020 18:13:52
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 18:13:52

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:13:35', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae8e7123-00c0-458f-a90d-494845a99236' User entered 'No (N)'	System	29 Sep 2020 18:13:52
	System	29 Sep 2020 18:13:52

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:13:39', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae8e7123-00c0-458f-a90d-494845a99236' User entered 'No (N)'	System	29 Sep 2020 18:13:52
	System	29 Sep 2020 18:13:52

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:13:44', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae8e7123-00c0-458f-a90d-494845a99236'	System	29 Sep 2020 18:13:52
User entered 'None (1)'	System	29 Sep 2020 18:13:52

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:13:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'ae8e7123-00c0-458f-a90d-494845a99236' User entered '29 Sep 2020 13:13'	System	29 Sep 2020 18:13:52
	System	29 Sep 2020 18:13:52

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 5'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:41', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'eb78e9a7-c452-480c-ba62-8ed9205a61ff'	System	01 Oct 2020 01:17:03
User entered 'None (1)'	System	01 Oct 2020 01:17:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:45', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'eb78e9a7-c452-480c-ba62-8ed9205a61ff' User entered 'No (N)'	System	01 Oct 2020 01:17:03
	System	01 Oct 2020 01:17:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:48', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'eb78e9a7-c452-480c-ba62-8ed9205a61ff' User entered 'No (N)'	System	01 Oct 2020 01:17:03
	System	01 Oct 2020 01:17:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:54', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'eb78e9a7-c452-480c-ba62-8ed9205a61ff' User entered 'None (1)'	System	01 Oct 2020 01:17:03
	System	01 Oct 2020 01:17:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:58', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'eb78e9a7-c452-480c-ba62-8ed9205a61ff' User entered '30 Sep 2020 20:16'	System	01 Oct 2020 01:17:03
	System	01 Oct 2020 01:17:03

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 6'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:27:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366ebcb4-cbf2-459e-9b51-82198d1abcd9'	System	02 Oct 2020 00:28:24
User entered 'None (1)'	System	02 Oct 2020 00:28:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:27:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366ebcb4-cbf2-459e-9b51-82198d1abcd9' User entered 'No (N)'	System	02 Oct 2020 00:28:24
	System	02 Oct 2020 00:28:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:27:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366ebcb4-cbf2-459e-9b51-82198d1abcd9'	System	02 Oct 2020 00:28:24
User entered 'No (N)'	System	02 Oct 2020 00:28:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:01', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366ebcb4-cbf2-459e-9b51-82198d1abcd9' User entered 'None (1)'	System	02 Oct 2020 00:28:24
	System	02 Oct 2020 00:28:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:19', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366ebcb4-cbf2-459e-9b51-82198d1abcd9' User entered '01 Oct 2020 19:28'	System	02 Oct 2020 00:28:24
	System	02 Oct 2020 00:28:24

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 7'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:38:23', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd84015d3-e05a-4683-b098-3fce1e8bc56d' User entered 'None (1)'	System	03 Oct 2020 03:38:53
	System	03 Oct 2020 03:38:53

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:38:35', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd84015d3-e05a-4683-b098-3fce1e8bc56d' User entered 'No (N)'	System	03 Oct 2020 03:38:53
	System	03 Oct 2020 03:38:53

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:38:41', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd84015d3-e05a-4683-b098-3fce1e8bc56d' User entered 'No (N)'	System	03 Oct 2020 03:38:53
	System	03 Oct 2020 03:38:53

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:38:47', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd84015d3-e05a-4683-b098-3fce1e8bc56d' User entered 'None (1)'	System	03 Oct 2020 03:38:53
	System	03 Oct 2020 03:38:53

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T22:38:51', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd84015d3-e05a-4683-b098-3fce1e8bc56d' User entered '02 Oct 2020 22:38'	System	03 Oct 2020 03:38:53
	System	03 Oct 2020 03:38:53

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:11:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8824f227-c169-47b0-a290-817dedca6ca2' User entered 'None (0)'	System	26 Sep 2020 17:12:24
	System	26 Sep 2020 17:12:24

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:11:52', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8824f227-c169-47b0-a290-817dedca6ca2' User entered 'None (0)'	System	26 Sep 2020 17:12:24
	System	26 Sep 2020 17:12:24

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:11:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8824f227-c169-47b0-a290-817dedca6ca2' User entered 'None (0)'	System	26 Sep 2020 17:12:24
	System	26 Sep 2020 17:12:24

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:12:01', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8824f227-c169-47b0-a290-817dedca6ca2'	System	26 Sep 2020 17:12:24
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:12:24

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:12:05', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8824f227-c169-47b0-a290-817dedca6ca2' User entered 'None (0)'	System	26 Sep 2020 17:12:24
	System	26 Sep 2020 17:12:24

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:12:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8824f227-c169-47b0-a290-817dedca6ca2' User entered 'None (0)'	System	26 Sep 2020 17:12:24
	System	26 Sep 2020 17:12:24

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:12:12', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8824f227-c169-47b0-a290-817dedca6ca2' User entered 'No (N)'	System	26 Sep 2020 17:12:24
	System	26 Sep 2020 17:12:24

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-26T12:12:18', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8824f227-c169-47b0-a290-817dedca6ca2' User entered '26 Sep 2020 12:12'	System	26 Sep 2020 17:12:24
	System	26 Sep 2020 17:12:24

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 11:55'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 14:25'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:30', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '2fa52707-0aa9-4055-94ed-fa48791a1195' User entered 'None (0)'	System	27 Sep 2020 13:51:08
	System	27 Sep 2020 13:51:08

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '2fa52707-0aa9-4055-94ed-fa48791a1195' User entered 'None (0)'	System	27 Sep 2020 13:51:08
	System	27 Sep 2020 13:51:08

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:39', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '2fa52707-0aa9-4055-94ed-fa48791a1195' User entered 'None (0)'	System	27 Sep 2020 13:51:08
	System	27 Sep 2020 13:51:08

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:45', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '2fa52707-0aa9-4055-94ed-fa48791a1195'	System	27 Sep 2020 13:51:08
User entered 'No interference with activity (1)'	System	27 Sep 2020 13:51:08

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:51', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '2fa52707-0aa9-4055-94ed-fa48791a1195' User entered 'None (0)'	System	27 Sep 2020 13:51:08
	System	27 Sep 2020 13:51:08

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:54', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '2fa52707-0aa9-4055-94ed-fa48791a1195' User entered 'None (0)'	System	27 Sep 2020 13:51:08
	System	27 Sep 2020 13:51:08

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:50:58', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '2fa52707-0aa9-4055-94ed-fa48791a1195' User entered 'No (N)'	System	27 Sep 2020 13:51:08
	System	27 Sep 2020 13:51:08

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T08:51:04', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '2fa52707-0aa9-4055-94ed-fa48791a1195' User entered '27 Sep 2020 08:51'	System	27 Sep 2020 13:51:08
	System	27 Sep 2020 13:51:08

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '26 Sep 2020 15:20'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 2'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:16', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e898a955-28ec-47f7-87ae-c1075d59ea7b' User entered 'None (0)'	System	27 Sep 2020 19:09:43
	System	27 Sep 2020 19:09:43

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:19', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e898a955-28ec-47f7-87ae-c1075d59ea7b' User entered 'None (0)'	System	27 Sep 2020 19:09:43
	System	27 Sep 2020 19:09:43

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:23', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e898a955-28ec-47f7-87ae-c1075d59ea7b' User entered 'None (0)'	System	27 Sep 2020 19:09:43
	System	27 Sep 2020 19:09:43

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:26', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e898a955-28ec-47f7-87ae-c1075d59ea7b' User entered 'None (0)'	System	27 Sep 2020 19:09:43
	System	27 Sep 2020 19:09:43

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:29', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e898a955-28ec-47f7-87ae-c1075d59ea7b' User entered 'None (0)'	System	27 Sep 2020 19:09:43
	System	27 Sep 2020 19:09:43

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:32', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e898a955-28ec-47f7-87ae-c1075d59ea7b' User entered 'None (0)'	System	27 Sep 2020 19:09:43
	System	27 Sep 2020 19:09:43

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:37', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e898a955-28ec-47f7-87ae-c1075d59ea7b' User entered 'No (N)'	System	27 Sep 2020 19:09:43
	System	27 Sep 2020 19:09:43

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-27T14:09:40', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'e898a955-28ec-47f7-87ae-c1075d59ea7b' User entered '27 Sep 2020 14:09'	System	27 Sep 2020 19:09:43
	System	27 Sep 2020 19:09:43

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 3'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:24:05', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a83afd85-92f9-45a7-9268-d8664b000bc5' User entered 'None (0)'	System	29 Sep 2020 00:24:38
	System	29 Sep 2020 00:24:38

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:24:09', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a83afd85-92f9-45a7-9268-d8664b000bc5' User entered 'None (0)'	System	29 Sep 2020 00:24:38
	System	29 Sep 2020 00:24:38

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:24:13', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a83afd85-92f9-45a7-9268-d8664b000bc5' User entered 'None (0)'	System	29 Sep 2020 00:24:38
	System	29 Sep 2020 00:24:38

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:24:16', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a83afd85-92f9-45a7-9268-d8664b000bc5' User entered 'None (0)'	System	29 Sep 2020 00:24:38
	System	29 Sep 2020 00:24:38

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:24:20', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a83afd85-92f9-45a7-9268-d8664b000bc5' User entered 'None (0)'	System	29 Sep 2020 00:24:38
	System	29 Sep 2020 00:24:38

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:24:23', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a83afd85-92f9-45a7-9268-d8664b000bc5' User entered 'None (0)'	System	29 Sep 2020 00:24:38
	System	29 Sep 2020 00:24:38

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:24:29', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a83afd85-92f9-45a7-9268-d8664b000bc5' User entered 'No (N)'	System	29 Sep 2020 00:24:38
	System	29 Sep 2020 00:24:38

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-28T19:24:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'a83afd85-92f9-45a7-9268-d8664b000bc5' User entered '28 Sep 2020 19:24'	System	29 Sep 2020 00:24:38
	System	29 Sep 2020 00:24:38

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 4'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:12:31', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dfc64436-710d-4617-bd39-da1dac45eaf0' User entered 'None (0)'	System	29 Sep 2020 18:13:19
	System	29 Sep 2020 18:13:19

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:12:36', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dfc64436-710d-4617-bd39-da1dac45eaf0' User entered 'None (0)'	System	29 Sep 2020 18:13:19
	System	29 Sep 2020 18:13:19

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:12:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dfc64436-710d-4617-bd39-da1dac45eaf0' User entered 'None (0)'	System	29 Sep 2020 18:13:19
	System	29 Sep 2020 18:13:19

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:12:48', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dfc64436-710d-4617-bd39-da1dac45eaf0' User entered 'None (0)'	System	29 Sep 2020 18:13:19
	System	29 Sep 2020 18:13:19

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:12:51', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dfc64436-710d-4617-bd39-da1dac45eaf0' User entered 'None (0)'	System	29 Sep 2020 18:13:19
	System	29 Sep 2020 18:13:19

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:12:54', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dfc64436-710d-4617-bd39-da1dac45eaf0' User entered 'None (0)'	System	29 Sep 2020 18:13:19
	System	29 Sep 2020 18:13:19

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:13:07', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dfc64436-710d-4617-bd39-da1dac45eaf0' User entered 'No (N)'	System	29 Sep 2020 18:13:19
	System	29 Sep 2020 18:13:19

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-29T13:13:13', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'dfc64436-710d-4617-bd39-da1dac45eaf0' User entered '29 Sep 2020 13:13'	System	29 Sep 2020 18:13:19
	System	29 Sep 2020 18:13:19

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 5'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:15:54', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '13a778b0-fac0-4c33-bcec-c918c46c16d7' User entered 'None (0)'	System	01 Oct 2020 01:16:36
	System	01 Oct 2020 01:16:36

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:15:58', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '13a778b0-fac0-4c33-bcec-c918c46c16d7' User entered 'None (0)'	System	01 Oct 2020 01:16:36
	System	01 Oct 2020 01:16:36

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:01', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '13a778b0-fac0-4c33-bcec-c918c46c16d7' User entered 'None (0)'	System	01 Oct 2020 01:16:36
	System	01 Oct 2020 01:16:36

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:05', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '13a778b0-fac0-4c33-bcec-c918c46c16d7' User entered 'None (0)'	System	01 Oct 2020 01:16:36
	System	01 Oct 2020 01:16:36

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:10', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '13a778b0-fac0-4c33-bcec-c918c46c16d7' User entered 'None (0)'	System	01 Oct 2020 01:16:36
	System	01 Oct 2020 01:16:36

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:13', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '13a778b0-fac0-4c33-bcec-c918c46c16d7' User entered 'None (0)'	System	01 Oct 2020 01:16:36
	System	01 Oct 2020 01:16:36

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:26', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '13a778b0-fac0-4c33-bcec-c918c46c16d7' User entered 'No (N)'	System	01 Oct 2020 01:16:36
	System	01 Oct 2020 01:16:36

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-09-30T20:16:30', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '13a778b0-fac0-4c33-bcec-c918c46c16d7' User entered '30 Sep 2020 20:16'	System	01 Oct 2020 01:16:36
	System	01 Oct 2020 01:16:36

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 6'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:28', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366f7d43-1ab4-40a4-850c-078df415fff1' User entered 'None (0)'	System	02 Oct 2020 00:29:09
	System	02 Oct 2020 00:29:09

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:31', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366f7d43-1ab4-40a4-850c-078df415fff1' User entered 'None (0)'	System	02 Oct 2020 00:29:09
	System	02 Oct 2020 00:29:09

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366f7d43-1ab4-40a4-850c-078df415fff1' User entered 'None (0)'	System	02 Oct 2020 00:29:09
	System	02 Oct 2020 00:29:09

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:38', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366f7d43-1ab4-40a4-850c-078df415fff1' User entered 'None (0)'	System	02 Oct 2020 00:29:09
	System	02 Oct 2020 00:29:09

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:41', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366f7d43-1ab4-40a4-850c-078df415fff1' User entered 'None (0)'	System	02 Oct 2020 00:29:09
	System	02 Oct 2020 00:29:09

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:45', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366f7d43-1ab4-40a4-850c-078df415fff1' User entered 'None (0)'	System	02 Oct 2020 00:29:09
	System	02 Oct 2020 00:29:09

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:28:50', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366f7d43-1ab4-40a4-850c-078df415fff1' User entered 'No (N)'	System	02 Oct 2020 00:29:09
	System	02 Oct 2020 00:29:09

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-01T19:29:06', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '366f7d43-1ab4-40a4-850c-078df415fff1' User entered '01 Oct 2020 19:29'	System	02 Oct 2020 00:29:09
	System	02 Oct 2020 00:29:09

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	26 Sep 2020 16:38:34
User entered 'Day 7'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T12:33:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d9fe7b-0391-404f-9c16-deac196382c0' User entered 'None (0)'	System	02 Oct 2020 17:33:59
	System	02 Oct 2020 17:33:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T12:33:36', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d9fe7b-0391-404f-9c16-deac196382c0' User entered 'None (0)'	System	02 Oct 2020 17:33:59
	System	02 Oct 2020 17:33:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T12:33:39', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d9fe7b-0391-404f-9c16-deac196382c0' User entered 'None (0)'	System	02 Oct 2020 17:33:59
	System	02 Oct 2020 17:33:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T12:33:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d9fe7b-0391-404f-9c16-deac196382c0' User entered 'None (0)'	System	02 Oct 2020 17:33:59
	System	02 Oct 2020 17:33:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T12:33:46', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d9fe7b-0391-404f-9c16-deac196382c0' User entered 'None (0)'	System	02 Oct 2020 17:33:59
	System	02 Oct 2020 17:33:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T12:33:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d9fe7b-0391-404f-9c16-deac196382c0' User entered 'None (0)'	System	02 Oct 2020 17:33:59
	System	02 Oct 2020 17:33:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T12:33:53', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d9fe7b-0391-404f-9c16-deac196382c0' User entered 'No (N)'	System	02 Oct 2020 17:33:59
	System	02 Oct 2020 17:33:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DEF6FD4A-64F4-4F60-B278-39BD441A7181)', Time: '2020-10-02T12:33:57', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '89d9fe7b-0391-404f-9c16-deac196382c0' User entered '02 Oct 2020 12:33'	System	02 Oct 2020 17:33:59
	System	02 Oct 2020 17:33:59

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 16:38:34

US3592247

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:23:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 16:38:34

US3592247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 22:27:28

US3592247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:54:37
User entered '4 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 22:27:28

US3592247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 22:27:28

US3592247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:37
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:27:28

US3592247

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:32:08
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 22:27:39

US3592247

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'l'	System	07 Oct 2020 22:27:39

US3592247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:30:11

US3592247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:54
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Oct 2020 15:30:27
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Oct 2020 15:30:27
User entered '10 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 15:30:27
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Oct 2020 15:30:11
User entered '17 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:30:11

US3592247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 15:30:11

US3592247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:54:54
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 15:30:11

US3592247

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:55:01
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 15:30:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 15:30:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 15:30:57
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 15:30:50
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 15:30:50

US3592247

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'l'	System	19 Oct 2020 15:30:57
User entered empty.	System	19 Oct 2020 15:30:50

US3592247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:31:08

US3592247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:12
User entered '17 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 15:31:08

US3592247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 15:31:08

US3592247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:12
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 15:31:08

US3592247

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 15:31:11

US3592247

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'l'	System	19 Oct 2020 15:31:11

US3592247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:07:43

US3592247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:26
User entered '28 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 17:07:43

US3592247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:55:26
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Nov 2020 17:07:43

US3592247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:23:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'VISIT3'	System	10 Nov 2020 17:07:43

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered '28 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered '14:10'	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '28 Oct 2020 14:10'	System	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered '98.7' F	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered '62'	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'bpm'	System	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered '16'	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'breaths/min'	System	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:47
User entered '107'	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 05:05:20
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:55:47
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Not clinically significant per investigator' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 15:08:54
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		10 Nov 2020 17:08:19
User entered '59'	(b) (4), (b) (6)	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'mmHg'	System	10 Nov 2020 17:08:19

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46

US3592247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:23:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46

US3592247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:23:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4)	13 Nov 2020 17:55:55
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:08:50

US3592247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:23:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:55:55
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:08:50

US3592247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:56:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:09:04

US3592247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:56:02
User entered '28 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 17:09:04

US3592247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:56:02
User entered '14:39'	(b) (4), (b) (6)	10 Nov 2020 17:09:04

US3592247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered '28 Oct 2020 14:39'	System	10 Nov 2020 17:09:04

US3592247

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:02:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:57:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:09:08

US3592247

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'I'	System	10 Nov 2020 17:09:08

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 64'	System	29 Aug 2020 19:01:06

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-10-29T16:31:26', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8b757797-5d69-4e61-ba3d-6edba594227e' User entered 'No (N)'	System	29 Oct 2020 21:31:47
	System	29 Oct 2020 21:31:47

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-10-29T16:31:30', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8b757797-5d69-4e61-ba3d-6edba594227e' User entered 'No (N)'	System	29 Oct 2020 21:31:47
	System	29 Oct 2020 21:31:47

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-10-29T16:31:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8b757797-5d69-4e61-ba3d-6edba594227e' User entered '29 Oct 2020 16:31:43'	System	29 Oct 2020 21:31:47
	System	29 Oct 2020 21:31:47

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 19:01:06

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 71'	System	29 Aug 2020 19:01:06

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-05T09:12:02', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '288113dd-1e49-44c6-abb7-ba0d75373195'	System	05 Nov 2020 15:12:29
User entered 'No (N)'	System	05 Nov 2020 15:12:29

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-05T09:12:10', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '288113dd-1e49-44c6-abb7-ba0d75373195'	System	05 Nov 2020 15:12:29
User entered 'No (N)'	System	05 Nov 2020 15:12:29

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-05T09:12:28', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '288113dd-1e49-44c6-abb7-ba0d75373195' User entered '05 Nov 2020 09:12:28'	System	05 Nov 2020 15:12:29
	System	05 Nov 2020 15:12:29

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 19:01:06

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered 'Day 78'	System	29 Aug 2020 19:01:06

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-12T07:29:24', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4754efa7-ed47-47dc-abe7-0de4b933c34f' User entered 'Yes (Y)'	System	12 Nov 2020 13:30:04
	System	12 Nov 2020 13:30:04

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-12T07:29:29', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4754efa7-ed47-47dc-abe7-0de4b933c34f' User entered 'No (N)'	System	12 Nov 2020 13:30:04
	System	12 Nov 2020 13:30:04

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-12T07:29:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4754efa7-ed47-47dc-abe7-0de4b933c34f' User entered 'No (N)'	System	12 Nov 2020 13:30:04
	System	12 Nov 2020 13:30:04

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-12T07:29:37', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4754efa7-ed47-47dc-abe7-0de4b933c34f' User entered 'Yes (Y)'	System	12 Nov 2020 13:30:04
	System	12 Nov 2020 13:30:04

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Please 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)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-12T07:29:48', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4754efa7-ed47-47dc-abe7-0de4b933c34f'	System	12 Nov 2020 13:30:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 13:30:04

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-12T07:29:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4754efa7-ed47-47dc-abe7-0de4b933c34f' User entered '12 Nov 2020 07:29:55'	System	12 Nov 2020 13:30:04
	System	12 Nov 2020 13:30:04

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 19:01:06

US3592247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:51:55
Data entry locked.	System	29 Aug 2020 19:01:06
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 19:01:06

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-19T15:25:37', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '7ba0f74f-f311-49c7-aa85-77b4a2f961a0' User entered 'Yes (Y)'	System	20 Nov 2020 02:25:46

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-19T15:25:43', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '7ba0f74f-f311-49c7-aa85-77b4a2f961a0' User entered 'No (N)'	System	20 Nov 2020 02:25:46

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-19T15:25:49', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '7ba0f74f-f311-49c7-aa85-77b4a2f961a0' User entered 'No (N)'	System	20 Nov 2020 02:25:46

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-19T15:25:57', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '7ba0f74f-f311-49c7-aa85-77b4a2f961a0' User entered 'Yes (Y)'	System	20 Nov 2020 02:25:46
	System	20 Nov 2020 02:25:46

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Please 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-19T20:25:17', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '7ba0f74f-f311-49c7-aa85-77b4a2f961a0'	System	20 Nov 2020 02:25:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Nov 2020 02:25:46

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-19T20:25:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '7ba0f74f-f311-49c7-aa85-77b4a2f961a0' User entered '19 Nov 2020 20:25:34'	System	20 Nov 2020 02:25:46
	System	20 Nov 2020 02:25:46

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-25T13:06:53', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'bf31a702-b76f-4fe6-b55a-2486ecec22f5'	System	25 Nov 2020 19:07:27
User entered 'No (N)'	System	25 Nov 2020 19:07:27

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-25T13:07:02', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'bf31a702-b76f-4fe6-b55a-2486ecec22f5'	System	25 Nov 2020 19:07:27
User entered 'No (N)'	System	25 Nov 2020 19:07:27

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-25T13:07:25', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'bf31a702-b76f-4fe6-b55a-2486ecec22f5' User entered '25 Nov 2020 13:07:25'	System	25 Nov 2020 19:07:27
	System	25 Nov 2020 19:07:27

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-30T10:34:13', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '83426bfb-1432-4181-9987-71230244f820' User entered 'No (N)'	System	30 Nov 2020 16:34:39

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-30T10:34:18', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '83426bfb-1432-4181-9987-71230244f820' User entered 'No (N)'	System	30 Nov 2020 16:34:39

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-11-30T10:34:34', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '83426bfb-1432-4181-9987-71230244f820' User entered '30 Nov 2020 10:34:34'	System	30 Nov 2020 16:34:39
	System	30 Nov 2020 16:34:39

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-09T12:01:01', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '43b0f151-da78-4374-808d-d9dc54791988'	System	09 Dec 2020 18:01:40
User entered 'No (N)'	System	09 Dec 2020 18:01:40

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-09T12:01:12', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '43b0f151-da78-4374-808d-d9dc54791988'	System	09 Dec 2020 18:01:40
User entered 'No (N)'	System	09 Dec 2020 18:01:40

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-09T12:01:33', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '43b0f151-da78-4374-808d-d9dc54791988'	System	09 Dec 2020 18:01:40
User entered '09 Dec 2020 12:01:33'	System	09 Dec 2020 18:01:40

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-14T09:23:22', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd60fa901-8695-4f3e-91a5-41a331b4494a' User entered 'No (N)'	System	14 Dec 2020 15:43:42

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-14T09:43:29', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd60fa901-8695-4f3e-91a5-41a331b4494a' User entered 'No (N)'	System	14 Dec 2020 15:43:42

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-14T09:43:37', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: 'd60fa901-8695-4f3e-91a5-41a331b4494a' User entered '14 Dec 2020 09:43:37'	System	14 Dec 2020 15:43:42
	System	14 Dec 2020 15:43:42

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-21T09:25:11', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '18ac7358-3ba8-45f5-ab55-3a311c18c9c9' User entered 'No (N)'	System	21 Dec 2020 15:25:30
	System	21 Dec 2020 15:25:30

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-21T09:24:56', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '18ac7358-3ba8-45f5-ab55-3a311c18c9c9' User entered 'No (N)'	System	21 Dec 2020 15:25:30
	System	21 Dec 2020 15:25:30

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-21T09:25:25', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '18ac7358-3ba8-45f5-ab55-3a311c18c9c9' User entered '21 Dec 2020 09:25:25'	System	21 Dec 2020 15:25:30
	System	21 Dec 2020 15:25:30

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-28T09:32:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '93f013fc-ba16-421a-8765-a60a53d3635f' User entered 'No (N)'	System	28 Dec 2020 15:33:17

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-28T09:33:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '93f013fc-ba16-421a-8765-a60a53d3635f' User entered 'No (N)'	System	28 Dec 2020 15:33:17

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2020-12-28T09:33:15', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '93f013fc-ba16-421a-8765-a60a53d3635f' User entered '28 Dec 2020 09:33:15'	System	28 Dec 2020 15:33:17
	System	28 Dec 2020 15:33:17

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-04T07:56:41', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a3cef15-c57f-4698-82fd-8490fb13b91b' User entered 'No (N)'	System	04 Jan 2021 13:57:25
	System	04 Jan 2021 13:57:25

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-04T07:56:50', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a3cef15-c57f-4698-82fd-8490fb13b91b' User entered 'No (N)'	System	04 Jan 2021 13:57:25

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-04T07:57:23', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a3cef15-c57f-4698-82fd-8490fb13b91b' User entered '04 Jan 2021 07:57:23'	System	04 Jan 2021 13:57:25
	System	04 Jan 2021 13:57:25

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-13T12:00:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '54c79e9e-cb35-4764-aa4e-49febde4bbea' User entered 'No (N)'	System	13 Jan 2021 18:01:16
	System	13 Jan 2021 18:01:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-13T12:01:02', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '54c79e9e-cb35-4764-aa4e-49febde4bbea' User entered 'No (N)'	System	13 Jan 2021 18:01:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-13T12:01:08', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '54c79e9e-cb35-4764-aa4e-49febde4bbea' User entered '13 Jan 2021 12:01:08'	System	13 Jan 2021 18:01:16
	System	13 Jan 2021 18:01:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-18T08:53:18', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8e5a7c78-b4f3-4710-9b63-956b5a18efae' User entered 'No (N)'	System	18 Jan 2021 14:53:34
	System	18 Jan 2021 14:53:34

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-18T08:53:22', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8e5a7c78-b4f3-4710-9b63-956b5a18efae' User entered 'No (N)'	System	18 Jan 2021 14:53:34

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-18T08:53:30', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '8e5a7c78-b4f3-4710-9b63-956b5a18efae' User entered '18 Jan 2021 08:53:30'	System	18 Jan 2021 14:53:34
	System	18 Jan 2021 14:53:34

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-25T09:00:01', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '26fcb0da-3691-40ac-ab4a-45c99288ec4d' User entered 'No (N)'	System	25 Jan 2021 15:00:16
	System	25 Jan 2021 15:00:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-25T09:00:07', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '26fcb0da-3691-40ac-ab4a-45c99288ec4d' User entered 'No (N)'	System	25 Jan 2021 15:00:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-01-25T09:00:14', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '26fcb0da-3691-40ac-ab4a-45c99288ec4d' User entered '25 Jan 2021 09:00:14'	System	25 Jan 2021 15:00:16
	System	25 Jan 2021 15:00:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-01T11:27:11', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a2d7a0a-cd24-4587-869f-63e9e973029b' User entered 'No (N)'	System	01 Feb 2021 17:27:24
	System	01 Feb 2021 17:27:24

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-01T11:27:16', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a2d7a0a-cd24-4587-869f-63e9e973029b' User entered 'No (N)'	System	01 Feb 2021 17:27:24
	System	01 Feb 2021 17:27:24

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-01T11:27:22', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '4a2d7a0a-cd24-4587-869f-63e9e973029b' User entered '01 Feb 2021 11:27:22'	System	01 Feb 2021 17:27:24
	System	01 Feb 2021 17:27:24

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-08T07:57:55', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '993408cc-5f1e-4cf7-9775-4968e4619301' User entered 'No (N)'	System	08 Feb 2021 13:58:11
	System	08 Feb 2021 13:58:11

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-08T07:58:02', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '993408cc-5f1e-4cf7-9775-4968e4619301' User entered 'No (N)'	System	08 Feb 2021 13:58:11

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-08T07:58:07', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '993408cc-5f1e-4cf7-9775-4968e4619301' User entered '08 Feb 2021 07:58:07'	System	08 Feb 2021 13:58:11
	System	08 Feb 2021 13:58:11

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-17T12:01:37', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '08e3e239-b394-4189-8130-b7a34c350d13'	System	19 Feb 2021 03:48:16
User entered 'No (N)'	System	19 Feb 2021 03:48:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-18T21:48:01', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '08e3e239-b394-4189-8130-b7a34c350d13'	System	19 Feb 2021 03:48:16
User entered 'No (N)'	System	19 Feb 2021 03:48:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-18T21:48:11', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '08e3e239-b394-4189-8130-b7a34c350d13' User entered '18 Feb 2021 21:48:11'	System	19 Feb 2021 03:48:16
	System	19 Feb 2021 03:48:16

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-24T14:33:03-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '64c5b72d-8a4b-4e1b-9d01-8f9eb5e87151' User entered 'No (N)'	System	24 Feb 2021 20:33:21
	System	24 Feb 2021 20:33:21

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-24T14:33:06-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '64c5b72d-8a4b-4e1b-9d01-8f9eb5e87151' User entered 'No (N)'	System	24 Feb 2021 20:33:21
	System	24 Feb 2021 20:33:21

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-02-24T14:33:16-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '64c5b72d-8a4b-4e1b-9d01-8f9eb5e87151'	System	24 Feb 2021 20:33:21
User entered '24 Feb 2021 20:33:16'	System	24 Feb 2021 20:33:21

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-03-03T14:33:44-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '06188546-213d-4d69-b155-98249c1dd067'	System	03 Mar 2021 20:33:59
User entered 'No (N)'	System	03 Mar 2021 20:33:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-03-03T14:33:49-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '06188546-213d-4d69-b155-98249c1dd067'	System	03 Mar 2021 20:33:59
User entered 'No (N)'	System	03 Mar 2021 20:33:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-03-03T14:33:55-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '06188546-213d-4d69-b155-98249c1dd067'	System	03 Mar 2021 20:33:59
User entered '03 Mar 2021 14:33:55'	System	03 Mar 2021 20:33:59

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-03-08T09:20:49-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '1f60bd46-f20a-4007-be32-b879ca065e07'	System	08 Mar 2021 15:20:58
User entered 'No (N)'	System	08 Mar 2021 15:20:58

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

Have you been exposed to someone with 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 (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-03-08T09:20:52-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '1f60bd46-f20a-4007-be32-b879ca065e07'	System	08 Mar 2021 15:20:58
User entered 'No (N)'	System	08 Mar 2021 15:20:58

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (800415E1-4FCE-41B2-9171-7F2BB0C4A9D2)', Time: '2021-03-08T09:20:55-06:00', User OID: 'PatientReportedOutcome (US3592247)', ODM File OID: '1f60bd46-f20a-4007-be32-b879ca065e07'	System	08 Mar 2021 15:20:58
User entered '08 Mar 2021 09:20:55'	System	08 Mar 2021 15:20:58

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:35:57

US3592247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:23:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:35:57
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:35:57

US3592247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 21:50:26

US3592247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:38
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Nov 2020 21:50:39
User entered '21 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 21:50:26

US3592247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	25 Nov 2020 21:50:26

US3592247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:38
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 21:50:26

US3592247

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:59:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 21:50:48

US3592247

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:33:46
User entered 'l'	System	25 Nov 2020 21:50:48

US3592247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:16:23
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:46:20

US3592247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:16:23
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:46:20

US3592247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:16:23
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:46:20

US3592247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:23:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:16:23
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:46:20

US3592247

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:16:23
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:46:28

US3592247

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:23:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:16:23
User entered 'l'	System	30 Dec 2020 15:46:28

US3592247

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:23:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:48:24
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:43:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 14:58:03
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 16:16:57

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:21
User entered 'USA-US103-2020-mRNA-1273-P301000008'	System	16 Nov 2020 14:58:16
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 14:58:16

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:03:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:03:45
Data point term sent to Coder	System	13 Nov 2020 15:02:21
User entered 'Bradycardia'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '10 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Apr 2021 21:11:28
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:11:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:11:28
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Apr 2021 21:10:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 07:35:28
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)	14 Apr 2021 14:40:07
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated ' (Site from System).	(b) (4), (b) (6)	13 Apr 2021 21:11:09
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 'updated ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 21:11:05
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	13 Apr 2021 21:10:51
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:10:51
User entered '16 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 21:10:51
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)	23 Mar 2021 19:51:18
User closed query 'PV Query: Please provide the event end date.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 19:51:18
Query 'PV Query: Please provide the event end date.' answered with 'AE is still ongoing' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 19:25:16
User opened query 'PV Query: Please provide the event end date.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:46:06
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User closed query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however, Hospital Discharge Date, or Admitted to ICU? is missing. Please leave this query open until the response can be updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 07:35:39
Query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however, Hospital Discharge Date, or Admitted to ICU? is missing. Please leave this query open until the response can be updated.' answered with 'discharge date completed ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 21:14:15
User opened query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however, Hospital Discharge Date, or Admitted to ICU? is missing. Please leave this query open until the response can be updated.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 03:56:40
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 03:54:14
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'This information is not available at this time' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 15:02:36
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	13 Nov 2020 15:02:17
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '10 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 21:10:51
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:10:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 21:10:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:10:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

US3592247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
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)	15 Apr 2021 07:36:03
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 'no medication taken for bradycardia ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 21:12:02
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:10:51
User entered '0' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 21:10:51
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)	28 Nov 2020 06:01:38
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 21:10:51
User entered '1' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 21:10:51
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User closed query 'PV Query: Please provide the final event outcome.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the final event outcome.' answered with 'upadted ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:40:17
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:11:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:11:28
User opened query 'PV Query: Please provide the final event outcome.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:46:32
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add cholelithiasis to the subject's medical history. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:02:36
User opened query 'PV Query: please review as to whether or not ventral hernia and ventral hernia repair with mesh should be added as medical history ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:02:31
User opened query 'PV Query: please review as to whether or not the mesh infection/abscess should be included as an SAE ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:02:19
User opened query 'PV Query: could you confirm if the subject had a PICC line placed, and if so, the date that it was inserted? ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:02:15
User opened query 'PV Query: please clarify if echocardiograms reported on 10, 11, and 12 Nov 2020 were actually electrocardiograms; if not, could the reports for the echocardiograms be sent to Safety_Moderna@iqvia.com? ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:02:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User closed query 'Per DM CLR: Narrative indicates that the subject had PICC and some medications. However, there are no corresponding Concomitant Procedure and Concomitant Medications record that match these information. Please update to record the corresponding procedure and medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 07:38:36
User closed query 'PV Query: Please provide course of events during hospitalization, and confirm if heart rate returned to normal range prior to discharge.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:41:14
User closed query 'PV Query: Please provide result of any EKGs performed in narrative or with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:41:01
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:40:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), and confirm if subject required surgical intervention (ie pacemaker placement).' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:40:46
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)	14 Apr 2021 14:40:35
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 14:40:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'diagnostic testing added to procedure page ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 21:18:26
Query 'PV Query: Please provide course of events during hospitalization, and confirm if heart rate returned to normal range prior to discharge.' answered with 'see narrative ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 21:17:20
Query 'Per DM CLR: Narrative indicates that the subject had PICC and some medications. However, there are no corresponding Concomitant Procedure and Concomitant Medications record that match these information. Please update to record the corresponding procedure and medications as appropriate. Otherwise, clarify.' answered with 'narrative updated ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 21:17:01
Query 'PV Query: Please provide result of any EKGs performed in narrative or with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com.' answered with 'repoorts emailed ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 21:16:50
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no testing found in records' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 21:16:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), and confirm if subject required surgical intervention (ie pacemaker placement).' answered with 'procedure page has been updated ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 21:15:48
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'hypertension, HYPERTRIGLYCERIDEMIA' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 21:15:26
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 21:13:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED ON 12NOV2020 TO REPORT BEING HOSPITALIZED DUE TO BRADYCARDIC HEART RATE OF 43 AND VERTIGO. SHE ALSO REPORTED ABDOMINAL PAIN FOR ONE MONTH. SHE LIVES IN A NURSING FACILITY. AT THE TIME OF THE CALL SHE IS BEING GIVEN ANTIBIOTICS, POTASSIUM, AND PERCOCET AND WILL HAVE A PICC LINE PLACED. MEDICAL RECORDS WILL BE OBTAINED FOR MORE INFORMATION Follow Up #1: Medical records received. Subject presented to ED with bradycardia and generalized weakness/fatigue. She reported abdominal pain x1 month. CT scan was obtained and revealed fluid collection within ventral mesh associated with ventral hernia repair concerning for infected mesh material with abscess. A portion of the bowel was also discovered to be adhered to abdominal wall. Secondary to mesh infection, cholelithiasis – mildly dilated common bile duct and intrahepatic biliary ductal dilatation was noted. Chest x-ray showed no evidence of acute cardiopulmonary abnormality. EKG on 10Nov2020 showed sinus bradycardia. EKG on 11NOV2020 showed atrial fibrillation replaced sinus rhythm compared to the day before. A CT guided abscess drainage was completed on 13NOV2020. Approximately 5 cc's of purulent material was aspirated and a JP drain was placed for continued drainage of the abscess. Pathology report not included in records at this time. Subject was given IV antibiotic ertapenem for mesh infection and started on amiodarone 200mg BID for atrial fibrillation. Subject was discharged with drain and requested to follow up with infectious disease physician and cardiologist as well as attending physician. Possibly more records to come.' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 21:13:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject had PICC and some medications. However, there are no corresponding Concomitant Procedure and Concomitant Medications record that match these information. Please update to record the corresponding procedure and medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 06:01:55
User opened query 'PV Query: Please provide course of events during hospitalization, and confirm if heart rate returned to normal range prior to discharge.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:47:03
User opened query 'PV Query: Please provide result of any EKGs performed in narrative or with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:46:55
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:46:47
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), and confirm if subject required surgical intervention (ie pacemaker placement).' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:46:40
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)	23 Nov 2020 15:46:23
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)	23 Nov 2020 15:46:15
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered 'Subject called on 12Nov2020 to report being hospitalized due to bradycardic heart rate of 43 and vertigo. She also reported abdominal pain for one month. She lives in a nursing facility. At the time of the call she is being given antibiotics, potassium, and Percocet and will have a PICC line placed. Medical records will be obtained for more information'	(b) (4), (b) (6)	13 Nov 2020 15:02:17

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 15:02:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:23:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 21:10:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:05:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:05:45
Data point term sent to Coder	System	13 Nov 2020 15:04:23
User entered 'Vertigo'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '10 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:03:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 15:03:31
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 15:03:31
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:03:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:23:30

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 15:03:25

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Abdominal abscess, LLT: Abdominal abscess - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 19:11:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 19:11:54
Data point term sent to Coder	System	13 Apr 2021 18:46:47
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 18:46:29
Coding entries removed.	(b) (4), (b) (6)	13 Apr 2021 18:46:29
User entered 'ABDOMINAL abscess' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 18:46:29
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:05:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:05:48
Data point term sent to Coder	System	13 Nov 2020 15:05:26
User entered 'Abdominal pain'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '10 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
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). 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 'medication added to conmed page' (Site from DM). 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). DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 07:39:38
	(b) (4), (b) (6)	13 Apr 2021 18:46:40
	(b) (4), (b) (6)	28 Nov 2020 06:02:12
	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:46:29
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 18:46:29
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:15
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	13 Nov 2020 15:04:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:15
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 15:04:30

US3592247

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:23:30

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	13 Nov 2020 15:04:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Apr 2021 19:21:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 19:21:07
Data point term sent to Coder	System	13 Apr 2021 18:57:55
User entered 'Hypokalemia'	(b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:23:30

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	13 Apr 2021 18:57:44

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
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.	(b) (4) Coder Import (b) (4)	13 Apr 2021 19:22:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 19:22:38
Data point term sent to Coder	System	13 Apr 2021 18:59:59
User entered 'Seasonal allergies'	(b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:23:30

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 18:59:57

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	13 Apr 2021 19:26:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 19:26:00
Data point term sent to Coder	System	13 Apr 2021 19:03:02
User entered 'Cholelithiasis'	(b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 19:02:43

US3592247

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:23:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	13 Apr 2021 19:02:43

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:23:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:59:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:44:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:02:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:06:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:06:10
Data point term sent to Coder	System	31 Aug 2020 21:04:24
User entered 'prolia'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'osteoporosis'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'I'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Other (OTHER)'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'injection'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'other (OTHER)'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '6 months'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '1 Feb 2019'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:03:32

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:05:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:05:36
Data point term sent to Coder	System	31 Aug 2020 21:04:24
User entered 'Norco'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'spinal stenosis'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User closed query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) 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)	13 Oct 2020 08:07:29
Query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:03:54
User entered '5/325' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 19:03:42
User opened query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) 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)	05 Oct 2020 09:13:05
User entered 'I'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 19:03:42
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'twice daily (BID)'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'un UNK 2009'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:04:08

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: GEMFIBROZIL, PRODUCTSYNONYM: LOPID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:07:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:07:37
Data point term sent to Coder	System	31 Aug 2020 21:06:27
User entered 'lopid'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#5) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:22:47
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#5) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'data entry error' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:04:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 19:04:21
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#5) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:13:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'hypertriglyceridemia'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '600'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'mg (mg)'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'un UNK 2016'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:05:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: MAXZIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 09:43:35
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 Sep 2020 09:43:35
Data point term sent to Coder	System	12 Sep 2020 19:57:20
User closed query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' (Site from System).	System	12 Sep 2020 19:57:06
Query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' answered with 'data corrected' (Site from System).	(b) (4), (b) (6)	12 Sep 2020 19:57:06
User entered 'maxide' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Sep 2020 19:57:00
User opened query 'DM-Coding: Please check the spelling of the medication. If the spelling is correct, enter the active ingredients in parentheses (...) following the drug name.' (Site from System).	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:11:36
Data point term sent to Coder	System	31 Aug 2020 21:06:27
User entered 'traxide'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'hypertension'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User closed query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) 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)	13 Oct 2020 08:00:33
Query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	08 Oct 2020 19:04:59
' answered with 'data updated' (Site from DM).		
User entered '75/50' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 19:04:54
User opened query 'Per DM CLR: Please note, this is a combination drug. Please update the dose and unit to include both components as applicable (e.g Dose= 40/1680; Dose Unit = mg) 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)	08 Oct 2020 12:03:24
User entered 'I'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 19:04:54
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'un UNK 2001'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:06:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:07:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:07:37
Data point term sent to Coder	System	31 Aug 2020 21:07:28
User entered 'coreg'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'hypertension'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered '6.25'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'mg (mg)'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'un UNK 2019'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:19:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:19:06
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:19:06
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 21:19:06
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User entered 'I'	System	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User entered 'I'	System	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:19
User entered '804 (804)'	System	31 Aug 2020 21:06:55

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
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) (b) (4)	31 Aug 2020 21:09:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:09:34
Data point term sent to Coder	System	31 Aug 2020 21:08:29
User entered 'tylenol'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'arthritis hand'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '500'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'mg (mg)'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'un UNK 1995'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:07:31

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:15:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:15:47
Data point term sent to Coder	System	31 Aug 2020 21:08:29
User entered 'ibuprofen'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'arthritis hand'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '200'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'mg (mg)'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'un UNK 1995'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:08:15

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:10:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:10:34
Data point term sent to Coder	System	31 Aug 2020 21:09:30
User entered 'multivitamin'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User closed query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify ' (Site from DM). Query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify ' answered with 'updated to yes ' (Site from DM). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	24 Mar 2021 07:29:52 22 Mar 2021 19:34:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:34:17
User opened query 'Per CDM: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 19:34:17
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 08:28:26
	(b) (4), (b) (6)	13 Nov 2020 17:44:46
	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'nutritional supplement'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'l'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'un UNK 1990'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:09:00

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
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) (b) (4)	13 Nov 2020 15:07:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 15:07:45
Data point term sent to Coder	System	13 Nov 2020 15:07:28
User entered 'Influenza vaccine'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (U) (4), (U) (6)	13 Nov 2020 17:44:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'Influenza prophylaxis'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered '0.5'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered '19 Oct 2020'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered '19 Oct 2020'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:44:46
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User entered empty.	System	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User entered empty.	System	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:23
User entered empty.	System	13 Nov 2020 15:07:21

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: ERTAPENEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 10:25:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:25:55
Data point term sent to Coder	System	13 Apr 2021 18:51:50
User entered 'ertapenem'	(b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'abdominal abscess'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'l'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:17:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 17:17:01
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:17:01
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 17:17:01
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User entered 'I'	System	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User entered 'I'	System	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:27
User entered '804 (804)'	System	13 Apr 2021 18:51:37

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Apr 2021 19:30:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 19:30:45
Data point term sent to Coder	System	13 Apr 2021 19:07:12
User entered 'Fexofenadine'	(b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Seasonal allergies'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '180'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 19:06:09

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Apr 2021 19:30:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 19:30:49
Data point term sent to Coder User entered 'Amiodarone'	System (b) (4), (b) (6)	13 Apr 2021 19:08:13 13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Atrial fibrillation'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '400'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '22 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User entered '2'	System	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User entered 'I'	System	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:15:30
User entered '804 (804)'	System	13 Apr 2021 19:08:12

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Apr 2021 19:31:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 19:31:11
Data point term sent to Coder	System	13 Apr 2021 19:10:15
User entered 'Amiodarone'	(b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Atrial fibrillation'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '400'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 19:09:20

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 07:41:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 07:41:52
Data point term sent to Coder	System	13 Apr 2021 19:11:17
User entered 'Augmentin (amoxicillin/clavulanate)'	(b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Abdominal abscess'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '875/125'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:23:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 19:11:16

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:23:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:40:30
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:46
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	13 Apr 2021 19:15:46
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 17:44:51
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 16:17:03

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:23:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:16:48

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:23:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'CT guided Abdominal abscess drainage'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:16:48

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:16:48

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:23:30

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:16:48

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:23:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:17:51

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:23:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Echocardiogram'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:17:51

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:17:51

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:23:30

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:17:51

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:23:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:29
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:18:10

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:23:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:29
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Echocardiogram'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:18:10

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:29
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:18:10

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:23:30

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:29
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:18:10

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:23:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:18:32

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:23:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Echocardiogram'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:18:32

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:18:32

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:23:30

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:33
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:18:32

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:23:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:06

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:23:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'CT Abdomen/pelvis'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:06

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:06

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:23:30

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:06

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:23:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:41
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:38

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:23:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:41
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Chest x-ray'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:38

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:23:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:41
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:38

US3592247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:23:30

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:41
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:57:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:19:38

US3592247

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:23:30

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:48:20
User closed query '□ Per CDM: As per IRT and EDC, subject received both doses in Part A. Therefore dosing was not discontinued in Part A. Please remove all information from this page. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:48:18
Query 'Data is required. Please complete.' answered with 'date removed per query' (Site from System).	Diandra Henriques (b) (4) (b) (4)	22 Apr 2021 16:27:02
Query '□ Per CDM: As per IRT and EDC, subject received both doses in Part A. Therefore dosing was not discontinued in Part A. Please remove all information from this page. Thank you' answered with 'data has been removed' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	22 Apr 2021 16:26:33
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 16:26:09
Un-reviewed for Data Management.	Diandra Henriques (b) (4) (b) (4)	22 Apr 2021 16:26:09
User entered empty; reason for change Data Entry Error	Diandra Henriques (b) (4) (b) (4)	22 Apr 2021 16:26:09
User opened query '□ Per CDM: As per IRT and EDC, subject received both doses in Part A. Therefore dosing was not discontinued in Part A. Please remove all information from this page. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 18:13:28
Reviewed for Data Management.	(b) (4), (b) (6)	21 Apr 2021 18:13:23
User entered '26 Dec 2020'	Diandra Henriques (b) (4) (b) (4)	13 Apr 2021 16:35:15

US3592247

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:23:30

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 13:48:21
Query 'Data is required. Please complete.' answered with 'date removed per query' (Site from System).	Diandra Henriques (b) (4)	22 Apr 2021 16:27:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Apr 2021 16:26:09
User entered empty; reason for change Data Entry Error	System	22 Apr 2021 16:26:09
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)'	Diandra Henriques (b) (4)	22 Apr 2021 16:26:09
	(b) (4)	13 Apr 2021 16:35:15

US3592247

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered empty; reason for change Data Entry Error	(b) (4)	
	Diandra Henriques (b) (4)	22 Apr 2021 16:26:09
User entered 'RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY'	(b) (4)	
	Diandra Henriques (b) (4)	13 Apr 2021 16:35:15
	(b) (4)	

US3592247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:23:30

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered '19 Jan 2021'	(b) (4) Diandra Henriques (b) (4)	13 Apr 2021 16:35:53

US3592247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:23:30

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)'	(b) (4) Diandra Henriques (b) (4)	13 Apr 2021 16:35:53

US3592247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:23:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY'	(b) (4) Diandra Henriques (b) (4)	13 Apr 2021 16:35:53

US3592247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:23:30

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered empty.	(b) (4) Diandra Henriques (b) (4)	13 Apr 2021 16:35:53

US3592247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:23:30

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered empty.	(b) (4) Diandra Henriques (b) (4)	13 Apr 2021 16:35:53

US3592247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:23:30

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered empty.	(b) (4) Diandra Henriques (b) (4)	13 Apr 2021 16:35:53

US3592247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:23:30

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:59
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered empty.	(b) (4) Diandra Henriques (b) (4)	13 Apr 2021 16:35:53

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'USA-US103-2020-MRNA-1273-P301000008'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'Yes (Y)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'Yes (Y)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Terry'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Poling'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
	(b) (4)	
User entered '1709 S Rock Rd'	System	14 Apr 2021 14:48:42
User entered '1709 S. Rock Road'	(b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Wichita'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
	(b) (4)	
User entered 'KS'	System	14 Apr 2021 14:48:42
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered '67207'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'US'	(b) (4) System	16 Nov 2020 14:58:55

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 14:48:42
User entered '1'	System	16 Nov 2020 14:58:55

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'USA-US103-2020-MRNA-1273-P301000008'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'Yes (Y)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'Yes (Y)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Terry'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Poling'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
	(b) (4)	
User entered '1709 S Rock Rd'	System	14 Apr 2021 14:48:42
User entered '1709 S. Rock Road'	(b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Wichita'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
	(b) (4)	
User entered 'KS'	System	14 Apr 2021 14:48:42
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered '67207'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'US'	(b) (4) System	16 Nov 2020 14:58:55

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 14:48:42
User entered '1'	System	16 Nov 2020 14:58:55

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:23:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered '16/Nov/2020 14:58'	(b) (4) System	16 Nov 2020 14:58:55

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:23:30

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.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'I'	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:55

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'USA-US103-2020-MRNA-1273-P301000008'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'Yes (Y)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'Yes (Y)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	16 Nov 2020 14:58:46
User entered 'No (N)'	System	16 Nov 2020 14:58:16

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Terry'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Poling'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
	(b) (4)	
User entered '1709 S Rock Rd'	System	14 Apr 2021 14:48:42
User entered '1709 S. Rock Road'	(b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'Wichita'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
	(b) (4)	
User entered 'KS'	System	14 Apr 2021 14:48:42
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered '67207'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:03:20

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'US'	(b) (4) System	16 Nov 2020 14:58:55

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:23:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Apr 2021 14:48:42
User entered '1'	System	16 Nov 2020 14:58:55

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:23:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered '14/Apr/2021 10:48'	(b) (4) System	14 Apr 2021 14:48:42

US3592247

Folder: SAE USA-US103-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:23:30

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.	Terry Poling (b) (4)	28 Apr 2021 09:44:22
User entered 'I'	(b) (4) (D) (4), (b) (6)	14 Apr 2021 14:48:42