

US3592111 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:19:37

All time stamps listed in this document are displayed in GMT

US3592111

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 07:23:45

Generated On: 10 Jun 2021 08:19:37

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[Participant ID](#)

US3592111

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

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US3592111

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3592111

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



US3592111

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3592111

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3592111

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

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Were any significant conditions reported?

Yes ☒

No ☐

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US3592111

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	HEARING LOSS BILATERAL
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3592111

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	MYOPIA BILATERAL
Start date (dd MMM yyyy)	UN UNK 1955
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1955
Start Year (derived)	1955
Stop Month and Year (derived)	
Stop Year (derived)	

US3592111

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	HYPEROPIA BILATERAL
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3592111

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3592111

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	CHRONIC COUGH
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3592111

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3592111

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

US3592111

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	FIBROCYSTIC BREAST DISEASE
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3592111

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	OSTEOARTHRITIS LEFT KNEE
Start date (dd MMM yyyy)	UN DEC 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3592111

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Condition	RESTYLANE REFYNE DERMAL FILLER 1 ML
Start date (dd MMM yyyy)	21 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	21 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3592111

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	17:53 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:53
Height (xxx.x)	168.0 cm
Weight (xxx.x)	76.5 kg
BMI (xxx.x)	27.10459 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	

US3592111

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3592111

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Date of assessment (dd MMM yyyy) 10 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) UN UNK 1997

Date of last menstruation unknown False



US3592111

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

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**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 ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

US3592111

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	True
<b>Specify</b>	SUBJECT GOES TO CHURCH ONCE A WEEK AND GOES TO THE GROCERY STORES AT LEAST ONCE A WEEK AND VOLUNTEERS AT A SCHOOL WITH CHILDREN ONCE A WEEK.

US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185380

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 ☒

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Height	ND - Not Done
Weight	ND - Not Done

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	17:53 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:53
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	19:38 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 19:38
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	108 mmHg
Diastolic Blood Pressure units	MMHG

US3592111

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

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.*



US3592111

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 19:07 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 19:07

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

US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 AUG 2020
Collection time (00:00-23:59)	12:30 (24 HR)
Collection date and time (derived)	10 AUG 2020 12:30

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:40	10 AUG 2020 16:40
Nasopharyngeal Swab 2	No		

US3592111

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 19:41

PC Open Date & Time

10 AUG 2020 19:27

PC Close Date & Time

10 AUG 2020 21:57

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 AUG 2020 22:52

PC Close Date & Time

11 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**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

98.6 °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

11 AUG 2020 17:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

12 AUG 2020 13:38

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59



US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**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

13 AUG 2020 14:37

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:07

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**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

98.4 °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

15 AUG 2020 12:27

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**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

16 AUG 2020 14:44

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 19:42

PC Open Date & Time

10 AUG 2020 19:27

PC Close Date & Time

10 AUG 2020 21:57

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

10 AUG 2020 22:52

PC Close Date & Time

11 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**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

11 AUG 2020 17:29

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**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

12 AUG 2020 13:38

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**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

13 AUG 2020 14:37

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**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

14 AUG 2020 14:08

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:28

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 7
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	16 AUG 2020 14:44
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**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 ☐

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 19:43
PC Open Date & Time	10 AUG 2020 19:27
PC Close Date & Time	10 AUG 2020 21:57

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**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 ☐

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 22:52

PC Close Date & Time

11 AUG 2020 11:59



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**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)

52 of 2527

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 17:30
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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

54 of 2527

EAB) (1725)

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:39
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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

56 of 2527

EAB) (1725)

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 14:38
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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 ☒

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 14:08
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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

60 of 2527

EAB) (1725)

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:28
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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 ☒

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 14:45
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:22:27

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:22:27

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 10:58
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	7 SEP 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	7 SEP 2020 11:47
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3592111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 SEP 2020

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

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

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) 7 SEP 2020

What was the treatment time? (00:00-23:59) 11:16 (24 HR)

Treatment Date and Time (derived) 7 SEP 2020 11:16

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

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 SEP 2020
Collection time (00:00-23:59)	11:05 (24 HR)
Collection date and time (derived)	7 SEP 2020 11:05



US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)			7 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:06	7 SEP 2020 11:06
Nasopharyngeal Swab 2	No		

US3592111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 11:49

PC Open Date & Time

07 SEP 2020 11:36

PC Close Date & Time

07 SEP 2020 14:06

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**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 97.9 °F

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

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

PC Time Stamp	08 SEP 2020 09:05
PC Open Date & Time	07 SEP 2020 15:01
PC Close Date & Time	08 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 09:06

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 14:49

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 13:15

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**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

97.7 °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

12 SEP 2020 13:58

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 16:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**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

07 SEP 2020 11:50

PC Open Date & Time

07 SEP 2020 11:36

PC Close Date & Time

07 SEP 2020 14:06

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**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

08 SEP 2020 09:06

PC Open Date & Time

07 SEP 2020 15:01

PC Close Date & Time

08 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**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

09 SEP 2020 09:06

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**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

10 SEP 2020 14:50

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**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

11 SEP 2020 13:15

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**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

12 SEP 2020 13:59

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**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

13 SEP 2020 16:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**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 ☐

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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

No ☒

Yes ☐

PC Time stamp	07 SEP 2020 11:50
PC Open Date & Time	07 SEP 2020 11:36
PC Close Date & Time	07 SEP 2020 14:06

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**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 ☐

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 09:06
PC Open Date & Time	07 SEP 2020 15:01
PC Close Date & Time	08 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**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

98 of 2527

EAB) (1725)

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 09:07
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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

100 of 2527

EAB) (1725)

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**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)

102 of 2527

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 14:50
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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

104 of 2527

EAB) (1725)

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 13:16
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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 ☒

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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

108 of 2527

EAB) (1725)

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 16:31
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:22:27

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:22:27

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:51:12

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:51:12

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:20:48

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:20:49

Generated On: 10 Jun 2021 08:19:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:20:49

Generated On: 10 Jun 2021 08:19:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	15:28 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 15:28
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:20:49

Generated On: 10 Jun 2021 08:19:37

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.*

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:20:49

Generated On: 10 Jun 2021 08:19:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	15:50 (24 HR)
Collection date and time (derived)	6 OCT 2020 15:50

US3592111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:20:49

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 07:37:29
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 12:24:26
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 16:18:07
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59



US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 NOV 2020 16:18:41
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 NOV 2020 18:40:26
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 NOV 2020 16:43:32
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 12:02:13
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 DEC 2020 07:39:30
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 DEC 2020 18:48:53
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 DEC 2020 17:02:56
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**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

25 DEC 2020 12:21:09

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 JAN 2021 12:34:49
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**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

06 JAN 2021 10:12:21

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 15:20:48
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**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

20 JAN 2021 08:48:26

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 JAN 2021 09:29:22
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**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

05 FEB 2021 12:01:18

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 12:16:23
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 13:52:26
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 14:11:07

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 08:15:15

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 08:15:43

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 10:22:00

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

<b>TIMEPOINT</b>	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 08:02:15
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 MAR 2021 08:04:37
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 APR 2021 09:18:46
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 APR 2021 22:58:46
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 08:09:08

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

<b>TIMEPOINT</b>	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 APR 2021 07:53:31
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 FEB 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

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17 JUL 2022 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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24 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

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31 JUL 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

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07 AUG 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

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28 AUG 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3592111

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:19:37

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
Yes	No	03 MAR 2021 08:14:57

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:45:42

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:45:42

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3592111

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3592111

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

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

Visit date (dd MMM yyyy)	22 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 14:36
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592111

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

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.*

US3592111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00-23:59)	14:55 (24 HR)
Collection date and time (derived)	22 FEB 2021 14:55

US3592111

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 07:23:46

Generated On: 10 Jun 2021 08:19:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3592111

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

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*

**US3592111**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:19:37**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592111

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:19:37

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

**US3592111**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 08:19:37**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3592111

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 07:23:45

Generated On: 10 Jun 2021 08:19:37

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

Visit date (dd MMM yyyy)	18 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3592111

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 07:23:45

Generated On: 10 Jun 2021 08:19:37

Date of updated informed consent (dd MMM yyyy) 18 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 18 JAN 2021

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 \_\_\_\_\_

US3592111

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 07:23:45

Generated On: 10 Jun 2021 08:19:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00-23:59)	08:55 (24 HR)
Collection date and time (derived)	18 JAN 2021 08:55

US3592111

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 07:23:45

Generated On: 10 Jun 2021 08:19:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	08:48
Collection Date and Time (derived)	18 JAN 2021 08:48



US3592111

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 15:48:00

Generated On: 10 Jun 2021 08:19:37

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

AEID	USA-US103-2020-MRNA-1273-P30 1000005
Adverse event	PERFORATED DIVERTICULITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	05 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

325 of 2527

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

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

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

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CRC WAS NOTIFIED OF  
SUBJECTS HOSPITALIZATION  
UPON RECEIVE MESSAGE  
FROM THE WEEKEND. TC TO  
SUBJECT MADE AT 0805 AND  
0840 TO OBTAIN MORE  
INFORMATION. SUBJECT IS  
CURRENTLY HOSPITALIZED AT  
ST FRANCIS HOSPITAL. PER  
SUBJECT REPORT SHE WAS  
EXPERIENCING ABDOMINAL  
PAIN ON 03NOV2020 AND  
PRESENTED TO ER AT  
APPROXIMATELY 0330. DURING  
THAT VISIT A CT SCAN WAS  
PERFORMED AND SUBJECT  
WAS TOLD SHE HAD  
DIVERTICULITIS WITH  
PERFORATION. SHE WAS GIVEN  
MORPHINE AND DILAUDID FOR  
PAIN CONTROL IN THE ER.  
SUBJECT STATED THAT THEY  
SENT HER HOME FROM ER  
ABOUT 2 HOURS LATER WITH  
AUGMENTIN AND  
HYDROCODONE AND  
INSTRUCTIONS TO FOLLOW UP  
WITH PCP. SUBJECT WAS NOT  
ABLE TO GET INTO HER PCPS  
OFFICE FOR A FOLLOW APPT  
UNTIL AFTERNOON ON  
THURSDAY 05NOV2020.  
DURING THAT VISIT SUBJECT  
PCP FELT IT NECESSARY TO  
DIRECTLY ADMIT SUBJECT TO  
THE HOSPITAL FOR FURTHER  
ASSESSMENTS AND

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

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TREATMENT. REPEAT CT SCAN  
DONE UPON ADMISSION ALSO  
IDENTIFIED AN ABSCESS IN  
THE BOWEL. SUBJECT  
CONTINUES TO BE ADMITTED  
TO HOSPITAL SHE IS ON A  
CLEAR LIQUID DIET AND  
RECEIVING MEDICATION FOR  
PAIN MANAGEMENT AND  
NAUSEA CONTROL. PER  
SUBJECT THE CURRENT PLAN  
IS TO MONITOR FOR  
IMPROVEMENTS/DECLINE  
WHILE SHE RECEIVES IV  
ANTIBIOTICS AND IV FLUIDS.,  
NO SURGERY HAS BEEN DONE  
AND THERE ARE NO PLANS  
FOR SURGERY AT THIS TIME.  
WILL OBTAIN MEDICAL  
RECORDS FOR MORE PRECISE  
INFORMATION. ADDITIONAL  
DURING TC SUBJECT  
CONFIRMED THAT SHE HAS NO  
KNOWN HISTORY OF  
DIVERTICULITIS OR ANY  
OTHER GI CONDITION PRIOR  
TO THIS.

DRAIN WAS PLACED ON  
10NOV2020 DUE TO INCREASED  
SIZE OF ABSCESS AND  
DISCONTINUED ON 12NOV2020.  
SUBJECT DISCHARGED TO  
HOME ON 15NOV2020. PER  
SUBJECT WAS SEEN IN  
SURGEON'S OFFICE ON  
18NOV2020 AND REFERRED TO

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

---

INFECTIOUS DISEASE  
SPECIALIST AND WAS SEEN  
10DEC2020. MEDICAL RECORDS  
REQUESTED FROM BOTH OF  
THESE PROVIDERS HOWEVER  
NONE RECEIVED AT THIS TIME.  
SITE WILL REQUEST AGAIN.

---

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

---

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

AEID

Adverse event

COLON 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)

05 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

Persistent or significant disability or incapacity False

PRODUCTION RELEASE (v12.003

330 of 2527

EAB) (1725)

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

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



US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

AEID

Adverse event

ABDOMINAL PAIN

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)

03 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)

30 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

332 of 2527

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

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

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

AEID

Adverse event

CONSTIPATION

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)

03 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)

03 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death ☐ False

Life threatening ☐ False

Requires inpatient or prolongation of existing Hospitalization ☐ False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

334 of 2527

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

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

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

AEID

Adverse event

ORAL CANDIDIASIS  
SECONDARY TO IV ANTIBIOTIC  
USE

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)

18 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)

25 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 False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐  
No ☐  
Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

336 of 2527

EAB) (1725)

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

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

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

AEID

Adverse event

NAUSEA

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)

05 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)

30 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

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

338 of 2527

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

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



US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

AEID	
Adverse event	CHOLELITHIASIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003  
EAB) (1725)

340 of 2527

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

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

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

AEID	
Adverse event	BILATERAL PLEURAL EFFUSIONS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

342 of 2527

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

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

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Data signed:** (b) (4) 28 Apr 2021 07:23:45

**Generated On: 10 Jun 2021 08:19:37**

---

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

Yes ☒

No ☐

---

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

---

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication TELMISARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

345 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

347 of 2527



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication LIOTHYRONINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

349 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

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

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

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)

351 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication CALCIUM

Prophylaxis Yes ☐  
No ☒

Indication NUTRITIONAL SUPPLEMENT

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

353 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication VITAMIN D

Prophylaxis Yes ☐  
No ☒

Indication NUTRITIONAL SUPPLEMENT

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)

355 of 2527



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC COUGH SECONDARY  
TO POST NASAL DRAINAGE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

357 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication FEXOFENADINE

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC COUGH SECONDARY  
TO POST NASAL DRAINAGE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

359 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

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)

361 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

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

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication AUGMENTIN (AMOXICILLIN / CLAVULANATE)

Prophylaxis Yes ☐  
No ☒

Indication COLON 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)

363 of 2527



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

365 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication OXYCODONE/ACETAMINOPHE  
N

Prophylaxis Yes ☐  
No ☒

Indication ADBOMINAL PAIN

Dose per administration 7.5/325

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

367 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	15 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA

Dose per administration 4

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)

369 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication ONDANSETRON 2 MG/ML

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA

Dose per administration 2

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)

371 of 2527



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication FLAGYL 5 MG/ML

Prophylaxis Yes ☐  
No ☒

Indication PERFORATED DIVERTICULITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

373 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication BACTRIM DS

Prophylaxis Yes ☐  
No ☒

Indication COLON ABSCESS

Dose per administration 800/160

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)

375 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication HYDROMORPHONE 1 MG/ML

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

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)

377 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication MIRALAX

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

379 of 2527



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication ROCEPHIN

Prophylaxis Yes ☐  
No ☒

Indication COLON 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)

381 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication ROXICODONE

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

383 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication FLUCONAZOLE SWISH  
SOLUTION 10 MG/ML

Prophylaxis Yes ☐  
No ☒

Indication ORAL CANDIDIASIS  
SECONDARY TO IV ANTIBIOTIC  
USE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

385 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication PROBIOTICS

Prophylaxis Yes ☒  
No ☐

Indication DIETARY 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)

387 of 2527



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 10

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

If dose unit is Other, specify OUNCES

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)

389 of 2527

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 30 Apr 2021 15:49:05

Generated On: 10 Jun 2021 08:19:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 03 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 15:48:01

Generated On: 10 Jun 2021 08:19:37

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 15:48:00

Generated On: 10 Jun 2021 08:19:37

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 DEC 2020	PLACEMENT OF WOUND DRAIN	Adverse Event	
3 DEC 2020	COMPUTED TOMOGRAPHY SCAN	Adverse Event	
4 DEC 2020	DRAIN REMOVAL	Adverse Event	
03 NOV 2020	CT ABDOMEN AND PELVIS	Adverse Event	
05 NOV 2020	CT ABDOMEN AND PELVIS	Adverse Event	
10 NOV 2020	CT GUIDED WOUND DRAIN PLACEMENT	Adverse Event	
12 NOV 2020	CT ABDOMEN AND PELVIS	Adverse Event	

US3592111

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:19:37

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

US3592111

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:19:37

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 07:23:45

Generated On: 10 Jun 2021 08:19:37

SAEID	USA-US103-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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



US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 07:23:45

Generated On: 10 Jun 2021 08:19:37

SAEID	USA-US103-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)	10/NOV/2020 17:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 07:23:45

Generated On: 10 Jun 2021 08:19:37

SAEID	USA-US103-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
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)	26/MAR/2021 09:51
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

US3592111 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

**US3592111**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:19:37**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:26:55
User entered 'US3592111'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:49:10

US3592111

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:13:49

US3592111

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:49:11

US3592111

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:13:49

**US3592111**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:19:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'SCRN'	System	11 Aug 2020 00:13:49



US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:49:12

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '73'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'YEARS'	System	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '73'	System	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00



US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:19:37

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:00

US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:14



US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Aug 2020'	System	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2020'	System	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:14

US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:49:11



US3592111

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:19:37

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'l'	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:40
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:19:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:48
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:12:53

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:15:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:15:26
Data point term sent to Coder	System	19 Aug 2020 18:14:07
User entered 'hearing loss bilateral'	(b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:30



US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jan 2014'	System	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2014'	System	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:13:30

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 06:36:25
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Coders Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\23.0.	(b) (4) (b) (4)	29 Sep 2020 19:21:46
User coded data point as Term Coded data point by User: Coders System - version MedDRA\23.0.	Coders Import (b) (4)	29 Sep 2020 19:21:46
Query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Sep 2020 19:20:55
' answered with 'data has been updated' (Site from DM).		
Data point term sent to Coders	System	29 Sep 2020 19:20:20
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 19:20:17
User entered 'MYOPIA bilateral' reason for change:	(b) (4), (b) (6)	29 Sep 2020 19:20:17
Data Entry Error		
User opened query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	28 Sep 2020 15:15:03
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Coders Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\23.0.	(b) (4) (b) (4)	19 Aug 2020 18:15:26

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Aug 2020 18:15:26
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 18:14:10
User entered 'myopia'	(b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 1955'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:59



US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:13:59

**US3592111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jan 1955'	System	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '1955'	System	19 Aug 2020 18:13:59

US3592111

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:13:59

**US3592111**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:13:59



US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query 'Per DM CLR: Please specify the location of HYPEROPIA (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 06:36:42
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 19:23:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 19:23:51
Data point term sent to Coder	System	29 Sep 2020 19:22:23
Query 'Per DM CLR: Please specify the location of HYPEROPIA (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	29 Sep 2020 19:21:47
' answered with 'data has been updated' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 19:21:32
User entered 'HYPEROPIA bilateral' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 19:21:32
User opened query 'Per DM CLR: Please specify the location of HYPEROPIA (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	28 Sep 2020 15:15:13
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:15:43

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Aug 2020 18:15:43
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 18:15:13
User entered 'hyperopia'	(b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jan 2007'	System	19 Aug 2020 18:14:32



**US3592111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2007'	System	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:14:32

**US3592111**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:14:32

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:16:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:16:59
Data point term sent to Coder	System	19 Aug 2020 18:15:18
User entered 'hypertension'	(b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:19:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:59



US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:14:59

**US3592111**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jan 2012'	System	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:19:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2012'	System	19 Aug 2020 18:14:59

**US3592111**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:14:59

**US3592111**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:14:59

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 15:54:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Apr 2021 15:54:07
Data point term sent to Coder	System	09 Apr 2021 15:45:59
User closed query 'DM-Coding: for term CHRONIC COUGH SECONDARY TO POST NASAL DRAINAGE, Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) CHRONIC COUGH 2) NASAL DRAINAGE or Nasal sinus drainage etc. ' (Site from System).	System	09 Apr 2021 15:45:21
Query 'DM-Coding: for term CHRONIC COUGH SECONDARY TO POST NASAL DRAINAGE, Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) CHRONIC COUGH 2) NASAL DRAINAGE or Nasal sinus drainage etc. ' answered with 'term updated' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 15:45:21
User entered 'CHRONIC COUGH' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:45:03
User opened query 'DM-Coding: for term CHRONIC COUGH SECONDARY TO POST NASAL DRAINAGE, Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) CHRONIC COUGH 2) NASAL DRAINAGE or Nasal sinus drainage etc. ' (Site from System).	Coder Import (b) (4)	31 Mar 2021 13:51:22
Data point term sent to Coder	System	25 Mar 2021 15:11:25
DataPoint Un-verified.	Diandra Henriques (b) (4)	25 Mar 2021 15:11:06
Coding entries removed.	Diandra Henriques (b) (4)	25 Mar 2021 15:11:06
Signature has been broken.	Diandra Henriques (b) (4)	25 Mar 2021 15:11:06

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

Condition

Audit	User	Time (GMT)
User entered 'CHRONIC COUGH SECONDARY TO POST NASAL DRAINAGE' reason for change:	Diandra Henriques (b) (4)	25 Mar 2021 15:11:06
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Chronic post nasal drip - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:53:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:53:11
Data point term sent to Coder	System	19 Aug 2020 18:17:21
User entered 'chronic cough due to post nasal drainage'	(b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 1988'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:16:46



US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jan 1988'	System	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '1988'	System	19 Aug 2020 18:16:46

**US3592111**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:16:46

US3592111

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:16:46



US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:18:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:18:23
Data point term sent to Coder	System	19 Aug 2020 18:17:22
User entered 'hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:19:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jan 2014'	System	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:19:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2014'	System	19 Aug 2020 18:17:17



**US3592111**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:17:17

**US3592111**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:17:17

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:19:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:19:59
Data point term sent to Coder	System	19 Aug 2020 18:18:26
User entered 'postmenopausal'	(b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 1997'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:59

**US3592111**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:17:59



US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jan 1997'	System	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:19:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '1997'	System	19 Aug 2020 18:17:59

**US3592111**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:17:59

**US3592111**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:17:59

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User coded data point as SOC: Reproductive system and breast disorders, HLT: Breast disorders, HLT: Benign and malignant breast neoplasms, PT: Fibrocystic breast disease, LLT: Fibrocystic breast disease - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:20:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 18:20:23
Data point term sent to Coder	System	19 Aug 2020 18:19:31
User entered 'fibrocystic breast disease'	(b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 2002'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:19:28

**US3592111**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:19:28



US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:19:28

**US3592111**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jan 2002'	System	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:19:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2002'	System	19 Aug 2020 18:19:28

**US3592111**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:19:28

**US3592111**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:19:28

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:22:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 18:22:32
Data point term sent to Coder	System	19 Aug 2020 18:21:35
User entered 'osteoarthritis left knee'	(b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un Dec 2014'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:20:41



US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:20:41

**US3592111**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:28:51
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Dec 2014'	System	19 Aug 2020 18:20:41

**US3592111**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2014'	System	19 Aug 2020 18:20:41

US3592111

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:20:41

**US3592111**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered empty.	System	19 Aug 2020 18:20:41



US3592111

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:19:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Skin cosmetic procedure, LLT: Skin cosmetic procedure - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	21 Apr 2021 08:43:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 08:43:53
Data point term sent to Coder	System	20 Apr 2021 19:27:07
User entered 'RESTYLANE REFYNE DERMAL FILLER 1 ML'	Diandra Henriques (b) (4)	20 Apr 2021 19:26:20

US3592111

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '21 Jul 2020'	(b) (4) Diandra Henriques (b) (4)	20 Apr 2021 19:26:20

US3592111

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '0'	(b) (4) Diandra Henriques (b) (4)	20 Apr 2021 19:26:20

US3592111

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:19:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	20 Apr 2021 19:26:37
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	20 Apr 2021 19:26:20
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	20 Apr 2021 19:26:20

US3592111

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '21 Jul 2020' reason for change: Data Entry Error	(b) (4)	
	Diandra Henriques (b) (4)	20 Apr 2021 19:26:37
User entered empty.	(b) (4)	
	Diandra Henriques (b) (4)	20 Apr 2021 19:26:20
	(b) (4)	

US3592111

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:19:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '0'	(b) (4) Diandra Henriques (b) (4)	20 Apr 2021 19:26:20

US3592111

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jul 2020'	System	20 Apr 2021 19:26:20

US3592111

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:19:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2020'	System	20 Apr 2021 19:26:20



**US3592111**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'Jul 2020'	System	20 Apr 2021 19:26:37
User entered empty.	System	20 Apr 2021 19:26:20

**US3592111**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '2020'	System	20 Apr 2021 19:26:37
User entered empty.	System	20 Apr 2021 19:26:20

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '17:53'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered '10 Aug 2020 17:53'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '168.0' cm	(b) (4)	(b) (4)
DataPoint set to visible.	(b) (4), (b) (6)	19 Aug 2020 18:22:24
	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '76.5' kg	(b) (4)	19 Aug 2020 18:22:24
DataPoint set to visible.	(b) (4), (b) (6) System	11 Aug 2020 00:14:19



US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
Amendment Manager: User entered '27.10459'	System	16 Sep 2020 23:50:59
User entered '27.1'	System	19 Aug 2020 18:22:24
DataPoint set to visible.	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'kg/m2'	System	19 Aug 2020 18:22:24
DataPoint set to visible.	System	11 Aug 2020 00:14:19

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 10:51:26
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 19:34:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 04:44:35
User entered '98.2' F	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered '69'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'bpm'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered '16'	(b) (4), (b) (6)	19 Aug 2020 18:22:24



US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'breaths/min'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered '146'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'mmHg'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:02
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:35
User entered '96'	(b) (4), (b) (6)	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User entered 'mmHg'	System	19 Aug 2020 18:22:24

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35

US3592111

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35

US3592111

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:07
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:09:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:22:50



US3592111

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:07
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:09:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 19:34:53
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:22:50

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:13
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:37

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:13
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:13
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:37

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:13
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:13
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:37

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:13
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:13
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'un UNK 1997'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:23:53



US3592111

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:19:37

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:13
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:23:53

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

**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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

**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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

**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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

**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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34



US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

**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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

**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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34



US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

**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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

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 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'l'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'l'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:19:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'subject goes to church once a week and goes to the grocery stores at least once a week and volunteers at a school with children once a week.'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:34

US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:11
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:51

US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:11
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:51



US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[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 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:27:11
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:28:51

US3592111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'VISIT1'	System	19 Aug 2020 18:28:51

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 23:59:09

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:27:39
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:27:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 23:59:09
User entered '185380' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 23:59:09

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 23:59:09

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

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 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

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 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:30:14



US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:30:14

US3592111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:29:53
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 18:34:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:09
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:24:26

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '168.0' cm	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '76.5' kg	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '168.0' cm	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '76.5' kg	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 18:33:19



US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '17:53'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '10 Aug 2020 17:53'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '69'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19



US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'bpm'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'breaths/min'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '146'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '96'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '168.0' cm	(b) (4), (b) (6)	19 Aug 2020 18:33:19



US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:19:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 16:53:37
User entered '76.5' kg	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 09:31:22
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'not clinically significant per investigator' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:34:00
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 18:33:19
User entered '19:38'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '10 Aug 2020 19:38'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19



US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '68'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'bpm'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'breaths/min'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 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)	20 Aug 2020 09:31:25
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 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)	19 Aug 2020 18:34:26
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Aug 2020 18:33:19
User entered '162'	(b) (4), (b) (6)	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:21
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query 'Diastolic Blood Pressure reported is out of range > 100 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)	20 Aug 2020 09:31:28
Query 'Diastolic Blood Pressure reported is out of range > 100 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)	19 Aug 2020 18:34:46
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		19 Aug 2020 18:33:19
User entered '108'	(b) (4), (b) (6)	19 Aug 2020 18:33:19



US3592111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	19 Aug 2020 18:33:19

US3592111

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:26
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 14:09:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:35:07

US3592111

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:26
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:09:24
User entered '10 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:35:07

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:50



US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '19:07'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '10 Aug 2020 19:07'	System	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:42
User entered 'ONCE'	System	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 00:14:50

US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:52
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:35:46

US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:52
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:35:46

US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:52
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '12:30'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:35:46



US3592111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '10 Aug 2020 12:30'	System	19 Aug 2020 18:35:46

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:57
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:57
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:57
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	17 Sep 2020 14:15:26
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	17 Sep 2020 14:15:26
User entered '16:40' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:15:26
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 18:38:00
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '10 Aug 2020 16:40'	System	17 Sep 2020 14:15:26
User entered empty.	System	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:57
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:38:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:38:00



US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:30:57
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	19 Aug 2020 18:38:35
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	19 Aug 2020 18:38:35
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 18:38:00
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered empty.	System	19 Aug 2020 18:38:00

US3592111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:39:18

US3592111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'l'	System	19 Aug 2020 18:39:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:41:05', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd496834e-07a7-47f8-a9fd-7e30fc920677'	System	11 Aug 2020 00:41:48
User entered 'Yes (Y)'	System	11 Aug 2020 00:41:48

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:41:18', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd496834e-07a7-47f8-a9fd-7e30fc920677' User entered '97.5'	System	11 Aug 2020 00:41:48
	System	11 Aug 2020 00:41:48

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:41:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd496834e-07a7-47f8-a9fd-7e30fc920677'	System	11 Aug 2020 00:41:48
User entered 'No (N)'	System	11 Aug 2020 00:41:48



US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:41:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd496834e-07a7-47f8-a9fd-7e30fc920677'	System	11 Aug 2020 00:41:48
User entered '10 Aug 2020 19:41'	System	11 Aug 2020 00:41:48

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 19:27'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 21:57'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41



US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 22:52'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 2'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:28:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'f2164950-a89f-4802-9a7d-4cc91612c37e' User entered 'Yes (Y)'	System	11 Aug 2020 22:28:50
	System	11 Aug 2020 22:28:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:28:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'f2164950-a89f-4802-9a7d-4cc91612c37e' User entered '98.6'	System	11 Aug 2020 22:28:50
	System	11 Aug 2020 22:28:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:28:39', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'f2164950-a89f-4802-9a7d-4cc91612c37e'	System	11 Aug 2020 22:28:50
User entered 'No (N)'	System	11 Aug 2020 22:28:50



US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:28:49', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'f2164950-a89f-4802-9a7d-4cc91612c37e' User entered '11 Aug 2020 17:28'	System	11 Aug 2020 22:28:50
	System	11 Aug 2020 22:28:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 3'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:37:43', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22f8f87b-6ed2-42ff-a968-202f20700c64'	System	12 Aug 2020 18:38:18
User entered 'Yes (Y)'	System	12 Aug 2020 18:38:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:37:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22f8f87b-6ed2-42ff-a968-202f20700c64' User entered '97.7'	System	12 Aug 2020 18:38:18
	System	12 Aug 2020 18:38:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:06', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22f8f87b-6ed2-42ff-a968-202f20700c64'	System	12 Aug 2020 18:38:18
User entered 'No (N)'	System	12 Aug 2020 18:38:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22f8f87b-6ed2-42ff-a968-202f20700c64'	System	12 Aug 2020 18:38:18
User entered '12 Aug 2020 13:38'	System	12 Aug 2020 18:38:18



US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 4'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:36:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bb8d3bd6-edd7-48b4-9bb0-f53e575f1b8d' User entered 'Yes (Y)'	System	13 Aug 2020 19:37:06
	System	13 Aug 2020 19:37:06

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:36:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bb8d3bd6-edd7-48b4-9bb0-f53e575f1b8d' User entered '97.7'	System	13 Aug 2020 19:37:06
	System	13 Aug 2020 19:37:06

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:36:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bb8d3bd6-edd7-48b4-9bb0-f53e575f1b8d' User entered 'No (N)'	System	13 Aug 2020 19:37:06
	System	13 Aug 2020 19:37:06

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:02', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bb8d3bd6-edd7-48b4-9bb0-f53e575f1b8d' User entered '13 Aug 2020 14:37'	System	13 Aug 2020 19:37:06
	System	13 Aug 2020 19:37:06

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 5'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:18', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3ef3ccbf-ceb0-413e-8354-bf40b87fa487' User entered 'Yes (Y)'	System	14 Aug 2020 19:07:39
	System	14 Aug 2020 19:07:39

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3ef3ccbf-ceb0-413e-8354-bf40b87fa487' User entered '97.9'	System	14 Aug 2020 19:07:39
	System	14 Aug 2020 19:07:39

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3ef3ccbf-ceb0-413e-8354-bf40b87fa487'	System	14 Aug 2020 19:07:39
User entered 'No (N)'	System	14 Aug 2020 19:07:39

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3ef3ccbf-ceb0-413e-8354-bf40b87fa487' User entered '14 Aug 2020 14:07'	System	14 Aug 2020 19:07:39
	System	14 Aug 2020 19:07:39

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 6'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:20', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22de2a16-a018-4500-aa23-1798d437a83b' User entered 'Yes (Y)'	System	15 Aug 2020 17:27:44
	System	15 Aug 2020 17:27:44

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22de2a16-a018-4500-aa23-1798d437a83b' User entered '98.4'	System	15 Aug 2020 17:27:44
	System	15 Aug 2020 17:27:44

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22de2a16-a018-4500-aa23-1798d437a83b' User entered 'No (N)'	System	15 Aug 2020 17:27:44
	System	15 Aug 2020 17:27:44

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:43', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '22de2a16-a018-4500-aa23-1798d437a83b' User entered '15 Aug 2020 12:27'	System	15 Aug 2020 17:27:44
	System	15 Aug 2020 17:27:44

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 7'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:43:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5e9dfbf1-d8c6-41ff-9b99-c5d672a34093'	System	16 Aug 2020 19:44:18
User entered 'Yes (Y)'	System	16 Aug 2020 19:44:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5e9dfbf1-d8c6-41ff-9b99-c5d672a34093' User entered '98.4'	System	16 Aug 2020 19:44:18
	System	16 Aug 2020 19:44:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5e9dfbf1-d8c6-41ff-9b99-c5d672a34093'	System	16 Aug 2020 19:44:18
User entered 'No (N)'	System	16 Aug 2020 19:44:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5e9dfbf1-d8c6-41ff-9b99-c5d672a34093' User entered '16 Aug 2020 14:44'	System	16 Aug 2020 19:44:18
	System	16 Aug 2020 19:44:18

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:10', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered 'None (1)'	System	11 Aug 2020 00:42:31



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered 'No (N)'	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:17', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered 'No (N)'	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0'	System	11 Aug 2020 00:42:31
User entered 'None (1)'	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e559b571-bcdc-44ea-9165-2306f556a8c0' User entered '10 Aug 2020 19:42'	System	11 Aug 2020 00:42:31
	System	11 Aug 2020 00:42:31

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 19:27'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 21:57'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 22:52'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 2'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:05', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11' User entered 'None (1)'	System	11 Aug 2020 22:29:33
	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11'	System	11 Aug 2020 22:29:33
User entered 'No (N)'	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11'	System	11 Aug 2020 22:29:33
User entered 'No (N)'	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11' User entered 'None (1)'	System	11 Aug 2020 22:29:33
	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6b8ca11f-e4b7-4248-9e71-ec288db4ec11' User entered '11 Aug 2020 17:29'	System	11 Aug 2020 22:29:33
	System	11 Aug 2020 22:29:33

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 3'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:22', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41' User entered 'None (1)'	System	12 Aug 2020 18:38:46
	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41' User entered 'No (N)'	System	12 Aug 2020 18:38:46
	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:34', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41' User entered 'No (N)'	System	12 Aug 2020 18:38:46
	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41' User entered 'None (1)'	System	12 Aug 2020 18:38:46
	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:45', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a7901c8-e8d4-4f03-968e-9a90e3c83a41' User entered '12 Aug 2020 13:38'	System	12 Aug 2020 18:38:46
	System	12 Aug 2020 18:38:46

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 4'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:20', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6cafd5a971a'	System	13 Aug 2020 19:37:42
User entered 'None (1)'	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6cafd5a971a' User entered 'No (N)'	System	13 Aug 2020 19:37:42
	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6cafd5a971a' User entered 'No (N)'	System	13 Aug 2020 19:37:42
	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6cafd5a971a' User entered 'None (1)'	System	13 Aug 2020 19:37:42
	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:40', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '06206eda-fced-4086-98ff-a6eafd5a971a' User entered '13 Aug 2020 14:37'	System	13 Aug 2020 19:37:42
	System	13 Aug 2020 19:37:42

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 5'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:54', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered 'None (1)'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:07:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered 'No (N)'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered 'No (N)'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:03', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered 'None (1)'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '003a1952-8c58-439d-8c2e-11ff09258098'	System	14 Aug 2020 19:08:32
User entered '14 Aug 2020 14:08'	System	14 Aug 2020 19:08:32

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 6'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered 'None (1)'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered 'No (N)'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered 'No (N)'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:27:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered 'None (1)'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:03', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bd196eea-e957-47d6-8cc2-028e88325a72'	System	15 Aug 2020 17:28:04
User entered '15 Aug 2020 12:28'	System	15 Aug 2020 17:28:04

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 7'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923'	System	16 Aug 2020 19:44:40
User entered 'None (1)'	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:25', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923' User entered 'No (N)'	System	16 Aug 2020 19:44:40
	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923' User entered 'No (N)'	System	16 Aug 2020 19:44:40
	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923'	System	16 Aug 2020 19:44:40
User entered 'None (1)'	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd27ae30a-3272-44e4-a1e3-4753cac10923' User entered '16 Aug 2020 14:44'	System	16 Aug 2020 19:44:40
	System	16 Aug 2020 19:44:40

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered 'None (0)'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered 'None (0)'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:42:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered 'None (0)'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered 'None (0)'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered 'None (0)'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered 'None (0)'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered 'No (N)'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-10T19:43:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '3a2e4966-b805-4b4f-8142-972eade15f8f' User entered '10 Aug 2020 19:43'	System	11 Aug 2020 00:43:31
	System	11 Aug 2020 00:43:31

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 19:27'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 21:57'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Aug 2020 22:52'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 2'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6' User entered 'None (0)'	System	11 Aug 2020 22:30:09
	System	11 Aug 2020 22:30:09



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:42', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6' User entered 'None (0)'	System	11 Aug 2020 22:30:09
	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6' User entered 'None (0)'	System	11 Aug 2020 22:30:09
	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:47', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6' User entered 'None (0)'	System	11 Aug 2020 22:30:09
	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6' User entered 'None (0)'	System	11 Aug 2020 22:30:09
	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6' User entered 'None (0)'	System	11 Aug 2020 22:30:09
	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:29:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6' User entered 'No (N)'	System	11 Aug 2020 22:30:09
	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-11T17:30:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd7e7eef7-463c-4c77-8470-479dd49094e6' User entered '11 Aug 2020 17:30'	System	11 Aug 2020 22:30:09
	System	11 Aug 2020 22:30:09

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 3'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9' User entered 'None (0)'	System	12 Aug 2020 18:39:25
	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9' User entered 'None (0)'	System	12 Aug 2020 18:39:25
	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:38:58', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9' User entered 'None (0)'	System	12 Aug 2020 18:39:25
	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:02', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9' User entered 'None (0)'	System	12 Aug 2020 18:39:25
	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:05', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9' User entered 'None (0)'	System	12 Aug 2020 18:39:25
	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9' User entered 'None (0)'	System	12 Aug 2020 18:39:25
	System	12 Aug 2020 18:39:25



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9' User entered 'No (N)'	System	12 Aug 2020 18:39:25
	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-12T13:39:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6c58b512-3661-483f-be81-2dfa2b839bc9' User entered '12 Aug 2020 13:39'	System	12 Aug 2020 18:39:25
	System	12 Aug 2020 18:39:25

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 4'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125' User entered 'None (0)'	System	13 Aug 2020 19:38:15
	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125' User entered 'None (0)'	System	13 Aug 2020 19:38:15
	System	13 Aug 2020 19:38:15



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:54', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125' User entered 'None (0)'	System	13 Aug 2020 19:38:15
	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:37:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'None (0)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:38:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered 'No (N)'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-13T14:38:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '7f1749f8-4f80-4baf-9ebc-3e03dbb73125'	System	13 Aug 2020 19:38:15
User entered '13 Aug 2020 14:38'	System	13 Aug 2020 19:38:15

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 5'	System	11 Aug 2020 00:14:50



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3' User entered 'None (0)'	System	14 Aug 2020 19:08:46
	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3' User entered 'None (0)'	System	14 Aug 2020 19:08:46
	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3' User entered 'None (0)'	System	14 Aug 2020 19:08:46
	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3' User entered 'None (0)'	System	14 Aug 2020 19:08:46
	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3' User entered 'None (0)'	System	14 Aug 2020 19:08:46
	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3' User entered 'None (0)'	System	14 Aug 2020 19:08:46
	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3' User entered 'No (N)'	System	14 Aug 2020 19:08:46
	System	14 Aug 2020 19:08:46

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-14T14:08:43', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb366818-d749-47ef-9529-1f5e3de397e3' User entered '14 Aug 2020 14:08'	System	14 Aug 2020 19:08:46
	System	14 Aug 2020 19:08:46



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 6'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0' User entered 'None (0)'	System	15 Aug 2020 17:28:34
	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0' User entered 'None (0)'	System	15 Aug 2020 17:28:34
	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:17', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0' User entered 'None (0)'	System	15 Aug 2020 17:28:34
	System	15 Aug 2020 17:28:34



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'None (0)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0'	System	15 Aug 2020 17:28:34
User entered 'No (N)'	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-15T12:28:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'b9ada657-2ce9-4cb7-b5f1-78ead718a0b0' User entered '15 Aug 2020 12:28'	System	15 Aug 2020 17:28:34
	System	15 Aug 2020 17:28:34

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 7'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152' User entered 'None (0)'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152' User entered 'None (0)'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17



US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152' User entered 'None (0)'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152' User entered 'None (0)'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:54', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152' User entered 'None (0)'	System	16 Aug 2020 19:45:17
	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'None (0)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:44:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered 'No (N)'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-08-16T14:45:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a7691553-1320-4076-ba57-beebb52e2152'	System	16 Aug 2020 19:45:17
User entered '16 Aug 2020 14:45'	System	16 Aug 2020 19:45:17

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:14:50

US3592111

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:16

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:16

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:16

US3592111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:16

US3592111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:36
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:40:46

US3592111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'l'	System	19 Aug 2020 18:40:46

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:11:49

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:11:49



US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:11:49

US3592111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:42
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:11:49

US3592111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:31:46
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:12:12

US3592111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'l'	System	26 Aug 2020 16:12:12

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:31:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:37:15

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:31:51
User entered '31 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 16:37:15

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:31:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Sep 2020 16:37:15

US3592111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:31:51
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 16:37:15



US3592111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:31:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 16:37:23

US3592111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'l'	System	01 Sep 2020 16:37:23

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:06
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:11:39

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:06
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:11:39

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[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 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:06
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:11:39

US3592111

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'VISIT2'	System	08 Sep 2020 18:11:39

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07



US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '10:58'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '7 Sep 2020 10:58'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '71'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'bpm'	System	08 Sep 2020 18:14:07



US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '14'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'breaths/min'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '133'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '88'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	29 Sep 2020 15:26:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 15:26:43
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	08 Sep 2020 18:14:07
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:14:07



US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '11:47'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '7 Sep 2020 11:47'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '81'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'bpm'	System	08 Sep 2020 18:14:07



US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'breaths/min'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '130'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '85'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	08 Sep 2020 18:14:07

US3592111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:14

US3592111

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:32:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:14:14



US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'MRNA-1273 OR PLACEBO'	System	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '11:16'	(b) (4) (b) (4), (b) (6)	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '7 Sep 2020 11:16'	System	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Sep 2020 16:18:36



US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:01
User entered 'ONCE'	System	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:19:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'INTRAMUSCULAR'	System	07 Sep 2020 16:18:36

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:06
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:13

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:06
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:13

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:06
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '11:05'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:13

US3592111

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '7 Sep 2020 11:05'	System	08 Sep 2020 18:16:13

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:12
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 18:16:25



US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:12
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:12
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '11:06'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '7 Sep 2020 11:06'	System	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:12
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:21:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:12
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	29 Sep 2020 15:21:15
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	29 Sep 2020 15:21:15
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	08 Sep 2020 18:16:25
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:19:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered empty.	System	08 Sep 2020 18:16:25

US3592111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:33:25
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:16:29



US3592111

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'I'	System	08 Sep 2020 18:16:29

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:48:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6cf219c8-006f-4fa4-a193-a9e96f362e80' User entered 'Yes (Y)'	System	07 Sep 2020 16:49:05
	System	07 Sep 2020 16:49:05

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:48:47', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6cf219c8-006f-4fa4-a193-a9e96f362e80' User entered '97.9'	System	07 Sep 2020 16:49:05
	System	07 Sep 2020 16:49:05

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:48:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6cf219c8-006f-4fa4-a193-a9e96f362e80' User entered 'No (N)'	System	07 Sep 2020 16:49:05
	System	07 Sep 2020 16:49:05

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:49:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6cf219c8-006f-4fa4-a193-a9e96f362e80' User entered '07 Sep 2020 11:49'	System	07 Sep 2020 16:49:05
	System	07 Sep 2020 16:49:05

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 11:36'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 14:06'	System	07 Sep 2020 16:18:36



US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:04:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '58211aba-6946-479b-80ba-24e086a919ff' User entered 'Yes (Y)'	System	08 Sep 2020 14:05:07
	System	08 Sep 2020 14:05:07

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:04:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '58211aba-6946-479b-80ba-24e086a919ff' User entered '97.9'	System	08 Sep 2020 14:05:07
	System	08 Sep 2020 14:05:07

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:04:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '58211aba-6946-479b-80ba-24e086a919ff' User entered 'No (N)'	System	08 Sep 2020 14:05:07
	System	08 Sep 2020 14:05:07

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '58211aba-6946-479b-80ba-24e086a919ff' User entered '08 Sep 2020 09:05'	System	08 Sep 2020 14:05:07
	System	08 Sep 2020 14:05:07

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 15:01'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 2'	System	07 Sep 2020 16:18:36



US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:05:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '76e5b291-b83c-470c-be5a-067eeb6f3cc6' User entered 'Yes (Y)'	System	09 Sep 2020 14:06:20
	System	09 Sep 2020 14:06:20

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '76e5b291-b83c-470c-be5a-067eeb6f3cc6' User entered '97.0'	System	09 Sep 2020 14:06:20
	System	09 Sep 2020 14:06:20

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '76e5b291-b83c-470c-be5a-067eeb6f3cc6'	System	09 Sep 2020 14:06:20
User entered 'No (N)'	System	09 Sep 2020 14:06:20

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '76e5b291-b83c-470c-be5a-067eeb6f3cc6' User entered '09 Sep 2020 09:06'	System	09 Sep 2020 14:06:20
	System	09 Sep 2020 14:06:20

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 3'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41



US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 4'	System	07 Sep 2020 16:18:36



US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:18', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '701558f3-e1c5-4b19-b52f-56f4457aad73' User entered 'Yes (Y)'	System	10 Sep 2020 19:49:49
	System	10 Sep 2020 19:49:49

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '701558f3-e1c5-4b19-b52f-56f4457aad73' User entered '97.5'	System	10 Sep 2020 19:49:49
	System	10 Sep 2020 19:49:49

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:36', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '701558f3-e1c5-4b19-b52f-56f4457aad73'	System	10 Sep 2020 19:49:49
User entered 'No (N)'	System	10 Sep 2020 19:49:49

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:45', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '701558f3-e1c5-4b19-b52f-56f4457aad73' User entered '10 Sep 2020 14:49'	System	10 Sep 2020 19:49:49
	System	10 Sep 2020 19:49:49

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 5'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '18d7833c-1359-462a-8cfc-9adf8c99eb96'	System	11 Sep 2020 18:15:25
User entered 'Yes (Y)'	System	11 Sep 2020 18:15:25



US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:11', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '18d7833c-1359-462a-8cfc-9adf8c99eb96' User entered '96.5'	System	11 Sep 2020 18:15:25
	System	11 Sep 2020 18:15:25

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '18d7833c-1359-462a-8cfc-9adf8c99eb96'	System	11 Sep 2020 18:15:25
User entered 'No (N)'	System	11 Sep 2020 18:15:25

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '18d7833c-1359-462a-8cfc-9adf8c99eb96'	System	11 Sep 2020 18:15:25
User entered '11 Sep 2020 13:15'	System	11 Sep 2020 18:15:25

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 6'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d20657-e431-4bc5-9240-08cbcc05ffca' User entered 'Yes (Y)'	System	12 Sep 2020 18:58:35
	System	12 Sep 2020 18:58:35

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d20657-e431-4bc5-9240-08cbcc05ffca' User entered '97.7'	System	12 Sep 2020 18:58:35
	System	12 Sep 2020 18:58:35



US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d20657-e431-4bc5-9240-08cbcc05ffca' User entered 'No (N)'	System	12 Sep 2020 18:58:35
	System	12 Sep 2020 18:58:35

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:34', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d20657-e431-4bc5-9240-08cbcc05ffca' User entered '12 Sep 2020 13:58'	System	12 Sep 2020 18:58:35
	System	12 Sep 2020 18:58:35

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 7'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:30:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'cc8a15bf-c7fe-4536-b4df-3d6a02621106'	System	13 Sep 2020 21:31:04
User entered 'Yes (Y)'	System	13 Sep 2020 21:31:04

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:30:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'cc8a15bf-c7fe-4536-b4df-3d6a02621106' User entered '98.1'	System	13 Sep 2020 21:31:04
	System	13 Sep 2020 21:31:04

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:30:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'cc8a15bf-c7fe-4536-b4df-3d6a02621106'	System	13 Sep 2020 21:31:04
User entered 'No (N)'	System	13 Sep 2020 21:31:04



US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'cc8a15bf-c7fe-4536-b4df-3d6a02621106' User entered '13 Sep 2020 16:31'	System	13 Sep 2020 21:31:04
	System	13 Sep 2020 21:31:04

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:49:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ca4e-4346-a08f-e55f542d3d95'	System	07 Sep 2020 16:50:14
User entered 'None (1)'	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:49:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ca4e-4346-a08f-e55f542d3d95'	System	07 Sep 2020 16:50:14
User entered 'No (N)'	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:49:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ca4e-4346-a08f-e55f542d3d95' User entered 'No (N)'	System	07 Sep 2020 16:50:14
	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:03', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ca4e-4346-a08f-e55f542d3d95'	System	07 Sep 2020 16:50:14
User entered 'None (1)'	System	07 Sep 2020 16:50:14



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2e30f6f6-ca4e-4346-a08f-e55f542d3d95' User entered '07 Sep 2020 11:50'	System	07 Sep 2020 16:50:14
	System	07 Sep 2020 16:50:14

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 11:36'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 14:06'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e'	System	08 Sep 2020 14:06:05
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:33', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e' User entered 'No (N)'	System	08 Sep 2020 14:06:05
	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:42', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e' User entered 'No (N)'	System	08 Sep 2020 14:06:05
	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:05:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e'	System	08 Sep 2020 14:06:05
User entered 'None (1)'	System	08 Sep 2020 14:06:05



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '252bc310-c305-4eb8-8b3a-42c481da693e' User entered '08 Sep 2020 09:06'	System	08 Sep 2020 14:06:05
	System	08 Sep 2020 14:06:05

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 15:01'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 2'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a' User entered 'None (1)'	System	09 Sep 2020 14:07:00
	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a' User entered 'No (N)'	System	09 Sep 2020 14:07:00
	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a' User entered 'No (N)'	System	09 Sep 2020 14:07:00
	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a' User entered 'None (1)'	System	09 Sep 2020 14:07:00
	System	09 Sep 2020 14:07:00



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd1ea8436-9b60-4fb9-a0a4-783a3383ed2a' User entered '09 Sep 2020 09:06'	System	09 Sep 2020 14:07:00
	System	09 Sep 2020 14:07:00

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 3'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 4'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c' User entered 'None (1)'	System	10 Sep 2020 19:50:13
	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c' User entered 'No (N)'	System	10 Sep 2020 19:50:13
	System	10 Sep 2020 19:50:13



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:49:58', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c' User entered 'No (N)'	System	10 Sep 2020 19:50:13
	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c' User entered 'None (1)'	System	10 Sep 2020 19:50:13
	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '69052fd0-3c57-4447-b86a-67e58fb48b3c' User entered '10 Sep 2020 14:50'	System	10 Sep 2020 19:50:13
	System	10 Sep 2020 19:50:13

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 5'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered 'None (1)'	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered 'No (N)'	System	11 Sep 2020 18:15:47



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered 'No (N)'	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2'	System	11 Sep 2020 18:15:47
User entered 'None (1)'	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:42', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '70e2be26-b1f4-4548-bc91-bb395d5901a2' User entered '11 Sep 2020 13:15'	System	11 Sep 2020 18:15:47
	System	11 Sep 2020 18:15:47

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 6'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:40', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9' User entered 'None (1)'	System	12 Sep 2020 18:59:02
	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9' User entered 'No (N)'	System	12 Sep 2020 18:59:02
	System	12 Sep 2020 18:59:02



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:47', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9' User entered 'No (N)'	System	12 Sep 2020 18:59:02
	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:58:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9' User entered 'None (1)'	System	12 Sep 2020 18:59:02
	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e4a867bd-100a-42f9-a4a6-6671aa9092f9' User entered '12 Sep 2020 13:59'	System	12 Sep 2020 18:59:02
	System	12 Sep 2020 18:59:02

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 7'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89'	System	13 Sep 2020 21:31:26
User entered 'None (1)'	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:10', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89'	System	13 Sep 2020 21:31:26
User entered 'No (N)'	System	13 Sep 2020 21:31:26



US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89' User entered 'No (N)'	System	13 Sep 2020 21:31:26
	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89'	System	13 Sep 2020 21:31:26
User entered 'None (1)'	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a9248371-78e1-406e-9a4c-8932f1b4fe89' User entered '13 Sep 2020 16:31'	System	13 Sep 2020 21:31:26
	System	13 Sep 2020 21:31:26

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c' User entered 'None (0)'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:17', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c' User entered 'None (0)'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c' User entered 'None (0)'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:22', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c' User entered 'None (0)'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c' User entered 'None (0)'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c' User entered 'None (0)'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afaf-1ef735abca3c' User entered 'No (N)'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-07T11:50:39', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '74d6b764-fc0b-4736-afa1-1ef735abca3c' User entered '07 Sep 2020 11:50'	System	07 Sep 2020 16:50:42
	System	07 Sep 2020 16:50:42

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 11:36'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 14:06'	System	07 Sep 2020 16:18:36



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3' User entered 'None (0)'	System	08 Sep 2020 14:06:45
	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3' User entered 'None (0)'	System	08 Sep 2020 14:06:45
	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3' User entered 'None (0)'	System	08 Sep 2020 14:06:45
	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3' User entered 'None (0)'	System	08 Sep 2020 14:06:45
	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3' User entered 'None (0)'	System	08 Sep 2020 14:06:45
	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3' User entered 'None (0)'	System	08 Sep 2020 14:06:45
	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:34', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3' User entered 'No (N)'	System	08 Sep 2020 14:06:45
	System	08 Sep 2020 14:06:45



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-08T09:06:42', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '368d9b26-61f3-4c4b-91e3-6ad391d458c3' User entered '08 Sep 2020 09:06'	System	08 Sep 2020 14:06:45
	System	08 Sep 2020 14:06:45

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '07 Sep 2020 15:01'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 2'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8' User entered 'None (0)'	System	09 Sep 2020 14:07:16
	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8' User entered 'None (0)'	System	09 Sep 2020 14:07:16
	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8' User entered 'None (0)'	System	09 Sep 2020 14:07:16
	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8' User entered 'None (0)'	System	09 Sep 2020 14:07:16
	System	09 Sep 2020 14:07:16



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:06:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8' User entered 'None (0)'	System	09 Sep 2020 14:07:16
	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:07:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8' User entered 'None (0)'	System	09 Sep 2020 14:07:16
	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:07:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8' User entered 'No (N)'	System	09 Sep 2020 14:07:16
	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-09T09:07:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'be83cd9e-bc2d-46e4-8a5e-0027cb0c3ea8' User entered '09 Sep 2020 09:07'	System	09 Sep 2020 14:07:16
	System	09 Sep 2020 14:07:16

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 3'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 16:18:36



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 4'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814' User entered 'None (0)'	System	10 Sep 2020 19:50:43
	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814' User entered 'None (0)'	System	10 Sep 2020 19:50:43
	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814' User entered 'None (0)'	System	10 Sep 2020 19:50:43
	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814' User entered 'None (0)'	System	10 Sep 2020 19:50:43
	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814' User entered 'None (0)'	System	10 Sep 2020 19:50:43
	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814' User entered 'None (0)'	System	10 Sep 2020 19:50:43
	System	10 Sep 2020 19:50:43



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814' User entered 'No (N)'	System	10 Sep 2020 19:50:43
	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-10T14:50:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '17488c08-9fb2-43d8-880c-071d30a67814' User entered '10 Sep 2020 14:50'	System	10 Sep 2020 19:50:43
	System	10 Sep 2020 19:50:43

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 5'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619' User entered 'None (0)'	System	11 Sep 2020 18:16:13
	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619' User entered 'None (0)'	System	11 Sep 2020 18:16:13
	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619' User entered 'None (0)'	System	11 Sep 2020 18:16:13
	System	11 Sep 2020 18:16:13



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619' User entered 'None (0)'	System	11 Sep 2020 18:16:13
	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619' User entered 'None (0)'	System	11 Sep 2020 18:16:13
	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:15:59', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619' User entered 'None (0)'	System	11 Sep 2020 18:16:13
	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:16:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619' User entered 'No (N)'	System	11 Sep 2020 18:16:13
	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-11T13:16:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '62e419ce-107d-45a7-af2f-d7f5524fe619'	System	11 Sep 2020 18:16:13
User entered '11 Sep 2020 13:16'	System	11 Sep 2020 18:16:13

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 6'	System	07 Sep 2020 16:18:36



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:05', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9' User entered 'None (0)'	System	12 Sep 2020 18:59:28
	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9' User entered 'None (0)'	System	12 Sep 2020 18:59:28
	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9' User entered 'None (0)'	System	12 Sep 2020 18:59:28
	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:11', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9' User entered 'None (0)'	System	12 Sep 2020 18:59:28
	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9' User entered 'None (0)'	System	12 Sep 2020 18:59:28
	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9' User entered 'None (0)'	System	12 Sep 2020 18:59:28
	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9' User entered 'No (N)'	System	12 Sep 2020 18:59:28
	System	12 Sep 2020 18:59:28

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-12T13:59:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6282a683-17e4-485a-9937-0db5268383b9' User entered '12 Sep 2020 13:59'	System	12 Sep 2020 18:59:28
	System	12 Sep 2020 18:59:28



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	07 Sep 2020 16:18:36
User entered 'Day 7'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc' User entered 'None (0)'	System	13 Sep 2020 21:31:54
	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc' User entered 'None (0)'	System	13 Sep 2020 21:31:54
	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:33', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc' User entered 'None (0)'	System	13 Sep 2020 21:31:54
	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:36', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc' User entered 'None (0)'	System	13 Sep 2020 21:31:54
	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:38', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc' User entered 'None (0)'	System	13 Sep 2020 21:31:54
	System	13 Sep 2020 21:31:54



US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:40', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc' User entered 'None (0)'	System	13 Sep 2020 21:31:54
	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc' User entered 'No (N)'	System	13 Sep 2020 21:31:54
	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-09-13T16:31:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'd89d982e-65ec-4944-bd9b-8cf0af91d7bc' User entered '13 Sep 2020 16:31'	System	13 Sep 2020 21:31:54
	System	13 Sep 2020 21:31:54

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 16:18:36

US3592111

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:19:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 16:18:36

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:33:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 14:15:06

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:33:54
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 14:15:06

US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:33:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 14:15:06



US3592111

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:33:54
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 14:15:06

US3592111

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:22:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:33:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 14:15:13

US3592111

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'l'	System	17 Sep 2020 14:15:13

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:34:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:44:09

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:34:07
User entered '22 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 16:44:09

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:34:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 16:44:09

US3592111

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:34:07
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:44:09

US3592111

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:34:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:44:13



US3592111

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'l'	System	23 Sep 2020 16:44:13

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:06:55

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:06:55

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:06:55

US3592111

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:29
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:06:55

US3592111

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:35
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 15:07:10

US3592111

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'l'	System	29 Sep 2020 15:07:10

US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:41
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:06:54



US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:41
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:06:54

US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[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 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:41
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:06:54

US3592111

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'VISIT3'	System	07 Oct 2020 21:06:54

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '15:28'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '6 Oct 2020 15:28'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51



US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '75'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'bpm'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '16'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'breaths/min'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '134'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	07 Oct 2020 21:07:51



US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:49
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '97'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'mmHg'	System	07 Oct 2020 21:07:51

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07

US3592111

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07

US3592111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:55
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:58

US3592111

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:34:55
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:07:58

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:35:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:08:06

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:35:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:08:06



US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:35:39
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered '15:50'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:08:06

US3592111

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered '6 Oct 2020 15:50'	System	07 Oct 2020 21:08:06

US3592111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:35:17
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:08:10

US3592111

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'I'	System	07 Oct 2020 21:08:10

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 64'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-10T07:36:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e9386ce2-ae1e-41cd-8b63-7e25fc541c44'	System	10 Oct 2020 12:37:30
User entered 'No (N)'	System	10 Oct 2020 12:37:30

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-10T07:37:08', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e9386ce2-ae1e-41cd-8b63-7e25fc541c44'	System	10 Oct 2020 12:37:30
User entered 'No (N)'	System	10 Oct 2020 12:37:30

**US3592111**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-10T07:37:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e9386ce2-ae1e-41cd-8b63-7e25fc541c44' User entered '10 Oct 2020 07:37:29'	System	10 Oct 2020 12:37:30
	System	10 Oct 2020 12:37:30



US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '10 Oct 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '14 Oct 2020 23:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 71'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-19T12:24:04', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2f6507cd-31ee-4321-a60a-d9f2867b1613'	System	19 Oct 2020 17:24:27
User entered 'No (N)'	System	19 Oct 2020 17:24:27

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-19T12:24:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2f6507cd-31ee-4321-a60a-d9f2867b1613'	System	19 Oct 2020 17:24:27
User entered 'No (N)'	System	19 Oct 2020 17:24:27

**US3592111**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-19T12:24:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '2f6507cd-31ee-4321-a60a-d9f2867b1613' User entered '19 Oct 2020 12:24:26'	System	19 Oct 2020 17:24:27
	System	19 Oct 2020 17:24:27

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '17 Oct 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '21 Oct 2020 23:59'	System	11 Aug 2020 00:14:50



US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 78'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-28T16:17:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bde07e6c-b7c0-4bcb-9b2a-b60e9c02ce6a' User entered 'No (N)'	System	28 Oct 2020 21:18:11
	System	28 Oct 2020 21:18:11

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-28T16:18:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bde07e6c-b7c0-4bcb-9b2a-b60e9c02ce6a'	System	28 Oct 2020 21:18:11
User entered 'No (N)'	System	28 Oct 2020 21:18:11

**US3592111**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-10-28T16:18:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'bde07e6c-b7c0-4bcb-9b2a-b60e9c02ce6a' User entered '28 Oct 2020 16:18:07'	System	28 Oct 2020 21:18:11
	System	28 Oct 2020 21:18:11

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '24 Oct 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '28 Oct 2020 23:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 92'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:07:12', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'Yes (Y)'	System	07 Nov 2020 22:18:49



US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:07:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'No (N)'	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:17:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'No (N)'	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:18:01', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'Yes (Y)'	System	07 Nov 2020 22:18:49

**US3592111**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:18:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4'	System	07 Nov 2020 22:18:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Nov 2020 22:18:49

**US3592111**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-07T16:18:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'a900d1f8-79cf-4a12-98e7-c8aad6c167e4' User entered '07 Nov 2020 16:18:41'	System	07 Nov 2020 22:18:49
	System	07 Nov 2020 22:18:49

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '07 Nov 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '11 Nov 2020 23:59'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered 'Day 99'	System	11 Aug 2020 00:14:50



US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:39:50', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'Yes (Y)'	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:39:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'No (N)'	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:40:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'No (N)'	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:40:08', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'Yes (Y)'	System	15 Nov 2020 00:40:44

**US3592111**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:40:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d'	System	15 Nov 2020 00:40:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 00:40:44

**US3592111**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-14T18:40:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '32ab9855-39b1-4e58-885c-58b920f7f25d' User entered '14 Nov 2020 18:40:26'	System	15 Nov 2020 00:40:44
	System	15 Nov 2020 00:40:44

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '14 Nov 2020 00:01'	System	11 Aug 2020 00:14:50

US3592111

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:10:41
Data entry locked.	System	11 Aug 2020 00:14:50
User entered '18 Nov 2020 23:59'	System	11 Aug 2020 00:14:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:42:39', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be' User entered 'Yes (Y)'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:42:47', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be' User entered 'No (N)'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:42:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be' User entered 'No (N)'	System	22 Nov 2020 22:43:45

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:43:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be'	System	22 Nov 2020 22:43:45
User entered 'Yes (Y)'	System	22 Nov 2020 22:43:45

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:43:17', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be'	System	22 Nov 2020 22:43:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 22:43:45

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-22T16:43:32', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9a56e5ad-961e-4862-bced-e4a8c92ef4be' User entered '22 Nov 2020 16:43:32'	System	22 Nov 2020 22:43:45
	System	22 Nov 2020 22:43:45

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:23:50

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-27T12:02:03', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'dc546f1f-f439-40a3-a386-22de4fbecf2a' User entered 'No (N)'	System	27 Nov 2020 18:02:16

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-27T12:02:07', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'dc546f1f-f439-40a3-a386-22de4fbecf2a' User entered 'No (N)'	System	27 Nov 2020 18:02:16

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-11-27T12:02:13', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'dc546f1f-f439-40a3-a386-22de4fbecf2a' User entered '27 Nov 2020 12:02:13'	System	27 Nov 2020 18:02:16
	System	27 Nov 2020 18:02:16

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:23:50



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-02T07:39:08', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '1b4471a0-2faf-4c83-b033-049d527a4bd3' User entered 'Yes (Y)'	System	02 Dec 2020 13:39:42
	System	02 Dec 2020 13:39:42

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-02T07:39:11', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '1b4471a0-2faf-4c83-b033-049d527a4bd3'	System	02 Dec 2020 13:39:42
User entered 'No (N)'	System	02 Dec 2020 13:39:42

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-02T07:39:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '1b4471a0-2faf-4c83-b033-049d527a4bd3' User entered 'No (N)'	System	02 Dec 2020 13:39:42
	System	02 Dec 2020 13:39:42

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-02T07:39:22', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '1b4471a0-2faf-4c83-b033-049d527a4bd3'	System	02 Dec 2020 13:39:42
User entered 'Yes (Y)'	System	02 Dec 2020 13:39:42

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-02T07:39:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '1b4471a0-2faf-4c83-b033-049d527a4bd3'	System	02 Dec 2020 13:39:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 13:39:42

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-02T07:39:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '1b4471a0-2faf-4c83-b033-049d527a4bd3' User entered '02 Dec 2020 07:39:30'	System	02 Dec 2020 13:39:42
	System	02 Dec 2020 13:39:42

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:23:50

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-12T18:48:27', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9baf9738-54ac-40fb-bca0-899e403a28f2' User entered 'Yes (Y)'	System	13 Dec 2020 00:49:03
	System	13 Dec 2020 00:49:03

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-12T18:48:31', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9baf9738-54ac-40fb-bca0-899e403a28f2'	System	13 Dec 2020 00:49:03
User entered 'No (N)'	System	13 Dec 2020 00:49:03

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-12T18:48:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9baf9738-54ac-40fb-bca0-899e403a28f2' User entered 'No (N)'	System	13 Dec 2020 00:49:03
	System	13 Dec 2020 00:49:03

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-12T18:48:41', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9baf9738-54ac-40fb-bca0-899e403a28f2' User entered 'Yes (Y)'	System	13 Dec 2020 00:49:03
	System	13 Dec 2020 00:49:03

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-12T18:48:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9baf9738-54ac-40fb-bca0-899e403a28f2'	System	13 Dec 2020 00:49:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 00:49:03

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-12T18:48:53', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9baf9738-54ac-40fb-bca0-899e403a28f2' User entered '12 Dec 2020 18:48:53'	System	13 Dec 2020 00:49:03
	System	13 Dec 2020 00:49:03

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-17T17:02:30', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '25a102dc-5c86-42c3-a913-77d939f32dcd' User entered 'Yes (Y)'	System	17 Dec 2020 23:03:06
	System	17 Dec 2020 23:03:06

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-17T17:02:34', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '25a102dc-5c86-42c3-a913-77d939f32dcd' User entered 'No (N)'	System	17 Dec 2020 23:03:06

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-17T17:02:39', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '25a102dc-5c86-42c3-a913-77d939f32dcd' User entered 'No (N)'	System	17 Dec 2020 23:03:06

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-17T17:02:45', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '25a102dc-5c86-42c3-a913-77d939f32dcd' User entered 'Yes (Y)'	System	17 Dec 2020 23:03:06
	System	17 Dec 2020 23:03:06

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-17T17:02:52', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '25a102dc-5c86-42c3-a913-77d939f32dcd'	System	17 Dec 2020 23:03:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 23:03:06

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-17T17:02:56', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '25a102dc-5c86-42c3-a913-77d939f32dcd' User entered '17 Dec 2020 17:02:56'	System	17 Dec 2020 23:03:06
	System	17 Dec 2020 23:03:06



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:23:50

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-25T12:20:51', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d0d2aa-cd68-438a-94f2-6cf273214ae5'	System	25 Dec 2020 18:21:12
User entered 'No (N)'	System	25 Dec 2020 18:21:12

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-25T12:20:55', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d0d2aa-cd68-438a-94f2-6cf273214ae5'	System	25 Dec 2020 18:21:12
User entered 'No (N)'	System	25 Dec 2020 18:21:12

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2020-12-25T12:21:09', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '98d0d2aa-cd68-438a-94f2-6cf273214ae5' User entered '25 Dec 2020 12:21:09'	System	25 Dec 2020 18:21:12
	System	25 Dec 2020 18:21:12

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-01T12:34:24', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '547d76ea-b37e-4942-8716-a135a5949d06'	System	01 Jan 2021 18:34:58
User entered 'Yes (Y)'	System	01 Jan 2021 18:34:58

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-01T12:34:29', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '547d76ea-b37e-4942-8716-a135a5949d06'	System	01 Jan 2021 18:34:58
User entered 'No (N)'	System	01 Jan 2021 18:34:58

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-01T12:34:33', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '547d76ea-b37e-4942-8716-a135a5949d06'	System	01 Jan 2021 18:34:58
User entered 'No (N)'	System	01 Jan 2021 18:34:58

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-01T12:34:37', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '547d76ea-b37e-4942-8716-a135a5949d06'	System	01 Jan 2021 18:34:58
User entered 'Yes (Y)'	System	01 Jan 2021 18:34:58

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-01T12:34:44', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '547d76ea-b37e-4942-8716-a135a5949d06'	System	01 Jan 2021 18:34:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 18:34:58

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-01T12:34:49', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '547d76ea-b37e-4942-8716-a135a5949d06' User entered '01 Jan 2021 12:34:49'	System	01 Jan 2021 18:34:58
	System	01 Jan 2021 18:34:58

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-06T10:12:10', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ce405b9b-5840-4463-b6e0-6799958f2d93'	System	06 Jan 2021 16:12:23
User entered 'No (N)'	System	06 Jan 2021 16:12:23

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-06T10:12:16', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ce405b9b-5840-4463-b6e0-6799958f2d93'	System	06 Jan 2021 16:12:23
User entered 'No (N)'	System	06 Jan 2021 16:12:23

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-06T10:12:21', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ce405b9b-5840-4463-b6e0-6799958f2d93' User entered '06 Jan 2021 10:12:21'	System	06 Jan 2021 16:12:23
	System	06 Jan 2021 16:12:23

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-13T15:20:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e90aaf40-904d-47a0-8b83-1f0b17b7b277'	System	13 Jan 2021 21:20:50
User entered 'No (N)'	System	13 Jan 2021 21:20:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-13T15:20:43', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e90aaf40-904d-47a0-8b83-1f0b17b7b277'	System	13 Jan 2021 21:20:50
User entered 'No (N)'	System	13 Jan 2021 21:20:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-13T15:20:48', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'e90aaf40-904d-47a0-8b83-1f0b17b7b277' User entered '13 Jan 2021 15:20:48'	System	13 Jan 2021 21:20:50
	System	13 Jan 2021 21:20:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:23:50

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-20T08:48:18', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'edcb5713-11e5-4855-8ed1-383dc7a3e71e' User entered 'No (N)'	System	20 Jan 2021 14:48:30
	System	20 Jan 2021 14:48:30

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-20T08:48:22', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'edcb5713-11e5-4855-8ed1-383dc7a3e71e' User entered 'No (N)'	System	20 Jan 2021 14:48:30



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-20T08:48:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'edcb5713-11e5-4855-8ed1-383dc7a3e71e' User entered '20 Jan 2021 08:48:26'	System	20 Jan 2021 14:48:30
	System	20 Jan 2021 14:48:30

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:23:50

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-27T09:13:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ae4f5696-3766-4d5b-a07e-9b607c7577ce' User entered 'Yes (Y)'	System	27 Jan 2021 15:29:33
	System	27 Jan 2021 15:29:33

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-27T09:13:25', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ae4f5696-3766-4d5b-a07e-9b607c7577ce' User entered 'No (N)'	System	27 Jan 2021 15:29:33

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-27T09:13:35', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ae4f5696-3766-4d5b-a07e-9b607c7577ce' User entered 'No (N)'	System	27 Jan 2021 15:29:33

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-27T09:13:46', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ae4f5696-3766-4d5b-a07e-9b607c7577ce' User entered 'Yes (Y)'	System	27 Jan 2021 15:29:33
	System	27 Jan 2021 15:29:33



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-27T09:27:57', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ae4f5696-3766-4d5b-a07e-9b607c7577ce'	System	27 Jan 2021 15:29:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Jan 2021 15:29:33

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-01-27T09:29:22', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ae4f5696-3766-4d5b-a07e-9b607c7577ce' User entered '27 Jan 2021 09:29:22'	System	27 Jan 2021 15:29:33
	System	27 Jan 2021 15:29:33

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-05T12:01:10', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '81bb4d1c-5458-42ac-ae32-720d484ea71a' User entered 'No (N)'	System	05 Feb 2021 18:02:31
	System	05 Feb 2021 18:02:31

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-05T12:01:14', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '81bb4d1c-5458-42ac-ae32-720d484ea71a' User entered 'No (N)'	System	05 Feb 2021 18:02:31
	System	05 Feb 2021 18:02:31

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-05T12:01:18', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '81bb4d1c-5458-42ac-ae32-720d484ea71a' User entered '05 Feb 2021 12:01:18'	System	05 Feb 2021 18:02:31
	System	05 Feb 2021 18:02:31



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-12T12:16:15', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '16d50242-8455-4c6a-be41-230f9bd5b846'	System	12 Feb 2021 18:16:24
User entered 'No (N)'	System	12 Feb 2021 18:16:24

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-12T12:16:20', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '16d50242-8455-4c6a-be41-230f9bd5b846'	System	12 Feb 2021 18:16:24
User entered 'No (N)'	System	12 Feb 2021 18:16:24

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-12T12:16:23', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '16d50242-8455-4c6a-be41-230f9bd5b846'	System	12 Feb 2021 18:16:24
User entered '12 Feb 2021 12:16:23'	System	12 Feb 2021 18:16:24

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-17T13:52:19', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '641250d7-0811-4065-98a5-77e6f52baf85' User entered 'No (N)'	System	17 Feb 2021 19:52:28
	System	17 Feb 2021 19:52:28

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-17T13:52:22', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '641250d7-0811-4065-98a5-77e6f52baf85'	System	17 Feb 2021 19:52:28
User entered 'No (N)'	System	17 Feb 2021 19:52:28

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-17T13:52:26', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '641250d7-0811-4065-98a5-77e6f52baf85' User entered '17 Feb 2021 13:52:26'	System	17 Feb 2021 19:52:28
	System	17 Feb 2021 19:52:28

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-24T08:10:52-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9cd8abc2-1856-415b-a506-b8479c115bef' User entered 'No (N)'	System	24 Feb 2021 14:11:10
	System	24 Feb 2021 14:11:10



US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-24T08:10:57-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9cd8abc2-1856-415b-a506-b8479c115bef' User entered 'No (N)'	System	24 Feb 2021 14:11:10
	System	24 Feb 2021 14:11:10

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-02-24T08:11:07-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '9cd8abc2-1856-415b-a506-b8479c115bef' User entered '24 Feb 2021 14:11:07'	System	24 Feb 2021 14:11:10
	System	24 Feb 2021 14:11:10

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:23:50

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-03T08:15:05-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ed07df0a-b0f2-4110-9d09-c5386251be52'	System	03 Mar 2021 14:15:18
User entered 'No (N)'	System	03 Mar 2021 14:15:18

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-03T08:15:11-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ed07df0a-b0f2-4110-9d09-c5386251be52'	System	03 Mar 2021 14:15:18
User entered 'No (N)'	System	03 Mar 2021 14:15:18

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-03T08:15:15-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'ed07df0a-b0f2-4110-9d09-c5386251be52'	System	03 Mar 2021 14:15:18
User entered '03 Mar 2021 08:15:15'	System	03 Mar 2021 14:15:18



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-10T08:15:34-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'c2141b25-5706-406b-8f95-f7e043a59187'	System	10 Mar 2021 14:15:46
User entered 'No (N)'	System	10 Mar 2021 14:15:46

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-10T08:15:38-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'c2141b25-5706-406b-8f95-f7e043a59187'	System	10 Mar 2021 14:15:46
User entered 'No (N)'	System	10 Mar 2021 14:15:46

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-10T08:15:43-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'c2141b25-5706-406b-8f95-f7e043a59187'	System	10 Mar 2021 14:15:46
User entered '10 Mar 2021 08:15:43'	System	10 Mar 2021 14:15:46

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-17T10:21:53-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '96cbbdfc-1a24-4ebb-a844-355d18a59bb4'	System	17 Mar 2021 15:22:05
User entered 'No (N)'	System	17 Mar 2021 15:22:05

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-17T10:21:57-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '96cbbdfc-1a24-4ebb-a844-355d18a59bb4'	System	17 Mar 2021 15:22:05
User entered 'No (N)'	System	17 Mar 2021 15:22:05

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-17T10:22:00-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '96cbbdfc-1a24-4ebb-a844-355d18a59bb4' User entered '17 Mar 2021 10:22:00'	System	17 Mar 2021 15:22:05
	System	17 Mar 2021 15:22:05

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-24T08:01:56-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '71cece89-3e7c-43e9-956e-eed04adb24a0'	System	24 Mar 2021 13:02:17
User entered 'No (N)'	System	24 Mar 2021 13:02:17



US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-24T08:02:06-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '71cece89-3e7c-43e9-956e-eed04adb24a0'	System	24 Mar 2021 13:02:17
User entered 'No (N)'	System	24 Mar 2021 13:02:17

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-24T08:02:15-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '71cece89-3e7c-43e9-956e-eed04adb24a0'	System	24 Mar 2021 13:02:17
User entered '24 Mar 2021 08:02:15'	System	24 Mar 2021 13:02:17

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:23:50

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-31T08:04:28-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6e8bd67a-5eb5-4719-962e-ba01ca5af3f5'	System	31 Mar 2021 13:04:42
User entered 'No (N)'	System	31 Mar 2021 13:04:42

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-31T08:04:33-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6e8bd67a-5eb5-4719-962e-ba01ca5af3f5'	System	31 Mar 2021 13:04:42
User entered 'No (N)'	System	31 Mar 2021 13:04:42

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-31T08:04:37-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '6e8bd67a-5eb5-4719-962e-ba01ca5af3f5'	System	31 Mar 2021 13:04:42
User entered '31 Mar 2021 08:04:37'	System	31 Mar 2021 13:04:42



US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-08T09:18:05-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '082e1878-8ca2-433a-90e6-21ca59bf3906'	System	08 Apr 2021 14:18:49
User entered 'Yes (Y)'	System	08 Apr 2021 14:18:49

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-08T09:18:11-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '082e1878-8ca2-433a-90e6-21ca59bf3906'	System	08 Apr 2021 14:18:49
User entered 'No (N)'	System	08 Apr 2021 14:18:49

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-08T09:18:37-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '082e1878-8ca2-433a-90e6-21ca59bf3906'	System	08 Apr 2021 14:18:49
User entered 'No (N)'	System	08 Apr 2021 14:18:49

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-08T09:18:41-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '082e1878-8ca2-433a-90e6-21ca59bf3906'	System	08 Apr 2021 14:18:49
User entered 'No (N)'	System	08 Apr 2021 14:18:49

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-08T09:18:46-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '082e1878-8ca2-433a-90e6-21ca59bf3906'	System	08 Apr 2021 14:18:49
User entered '08 Apr 2021 09:18:46'	System	08 Apr 2021 14:18:49



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:23:50

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:57:31-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'Yes (Y)'	System	15 Apr 2021 03:58:56

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:57:35-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'No (N)'	System	15 Apr 2021 03:58:56

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:57:47-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'Yes (Y)'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'l'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'l'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'l'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'l'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:24-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '0'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Please 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:34-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Apr 2021 03:58:56



US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:43-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered 'No (N)'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-14T22:58:46-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: 'eb0f4341-d049-4ad5-9c04-cb312892c683'	System	15 Apr 2021 03:58:56
User entered '14 Apr 2021 22:58:46'	System	15 Apr 2021 03:58:56

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-21T08:08:56-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '699fcadc-42ec-4cc3-86ba-930ec0960d78'	System	21 Apr 2021 13:09:19
User entered 'No (N)'	System	21 Apr 2021 13:09:19

US3592111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:19:37

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-21T08:09:00-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '699fcadc-42ec-4cc3-86ba-930ec0960d78'	System	21 Apr 2021 13:09:19
User entered 'No (N)'	System	21 Apr 2021 13:09:19

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-21T08:09:08-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '699fcadc-42ec-4cc3-86ba-930ec0960d78' User entered '21 Apr 2021 08:09:08'	System	21 Apr 2021 13:09:19
	System	21 Apr 2021 13:09:19



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:23:50

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-28T07:53:23-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '413d83c7-74e1-4283-9278-f4073312719c'	System	29 Apr 2021 00:04:21
User entered 'No (N)'	System	29 Apr 2021 00:04:21

US3592111

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

Have you been exposed to someone with 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 (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-28T07:53:27-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '413d83c7-74e1-4283-9278-f4073312719c'	System	29 Apr 2021 00:04:21
User entered 'No (N)'	System	29 Apr 2021 00:04:21

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-04-28T07:53:31-05:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '413d83c7-74e1-4283-9278-f4073312719c'	System	29 Apr 2021 00:04:21
User entered '28 Apr 2021 07:53:31'	System	29 Apr 2021 00:04:21

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:23:50



**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:23:50

**US3592111**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:19:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:23:50
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:23:50

US3592111

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:19:37**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:11:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-03T08:14:13-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5fd05171-a759-4140-8605-57dc9eb8c836'	System	03 Mar 2021 14:15:10
User entered 'Yes (Y)'	System	03 Mar 2021 14:15:10

US3592111

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:19:37**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:11:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-03T08:14:25-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5fd05171-a759-4140-8605-57dc9eb8c836'	System	03 Mar 2021 14:15:10
User entered 'No (N)'	System	03 Mar 2021 14:15:10

US3592111

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:19:37

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:11:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (133C108A-E1A2-4111-B974-56E377135298)', Time: '2021-03-03T08:14:57-06:00', User OID: 'PatientReportedOutcome (US3592111)', ODM File OID: '5fd05171-a759-4140-8605-57dc9eb8c836' User entered '03 Mar 2021 08:14:57'	System	03 Mar 2021 14:15:10
	System	03 Mar 2021 14:15:10

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:45:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Oct 2020 15:08:29



US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:45:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:28
User entered '30 Oct 2020'	(b) (4), (b) (6)	31 Oct 2020 15:08:29

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:45:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Oct 2020 15:08:29

US3592111

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:45:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:28
User entered empty.	(b) (4), (b) (6)	31 Oct 2020 15:08:29

US3592111

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:45:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Oct 2020 15:08:56

US3592111

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:21:07
User entered 'l'	System	31 Oct 2020 15:08:56

**US3592111**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:19:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 22:20:38

US3592111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:39
User entered '06 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 22:20:48
User entered '5 Dec 2020'	(b) (4), (b) (6)	18 Jan 2021 22:20:38

US3592111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Jan 2021 22:20:38



US3592111

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:39
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 22:20:38

US3592111

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 22:21:02

US3592111

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User entered 'l'	System	18 Jan 2021 22:21:02

US3592111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 22:22:07

US3592111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:49
User entered '4 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 22:22:07

US3592111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Jan 2021 22:22:07

US3592111

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:49
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 22:22:07

US3592111

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 22:22:14



US3592111

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User entered 'l'	System	18 Jan 2021 22:22:14

US3592111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 20:36:23

US3592111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:59
User entered '4 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 20:36:23

US3592111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 20:36:23

US3592111

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:19:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:36:59
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 20:36:23

US3592111

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 20:37:30

US3592111

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:29
User entered 'l'	System	23 Feb 2021 20:37:30

US3592111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 20:38:04



US3592111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:09
User entered '22 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 20:38:04

US3592111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:09
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Feb 2021 20:38:04

US3592111

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User entered 'VISIT4'	System	23 Feb 2021 20:38:04

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Yes (Y)'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '22 Feb 2021'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '14:36'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User entered '22 Feb 2021 14:36'	System	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '36.5' C	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16



US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Oral (Oral)'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered empty.	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '77'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User entered 'bpm'	System	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '16'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User entered 'breaths/min'	System	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '117'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User entered 'mmHg'	System	06 Apr 2021 20:16:16



US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '83'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User entered 'mmHg'	System	06 Apr 2021 20:16:16

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45

US3592111

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:19:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45

US3592111

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:13
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 20:38:31

US3592111

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:19:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:13
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 20:38:31

US3592111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Yes (Y)'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:33

US3592111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '22 Feb 2021'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:33



US3592111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '14:55'	(b) (4) Diandra Henriques (b) (4)	06 Apr 2021 20:16:33

US3592111

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User entered '22 Feb 2021 14:55'	System	06 Apr 2021 20:16:33

US3592111

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 20:38:52

US3592111

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:19:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:06:45
User entered 'I'	System	23 Feb 2021 20:38:52

US3592111

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:21
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 22:23:02

US3592111

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:21
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:30
User entered '18 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 22:23:02

US3592111

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:21
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Jan 2021 22:23:02

US3592111

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

Form: Visit Date

Generated On: 10 Jun 2021 08:19:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:21
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 22:23:02



US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:23:19

US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:01:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:41:50

US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:23:19

US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:01:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:41:50

US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:23:19

US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:23:19

US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 01:41:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 22:23:19

US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 01:41:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 22:23:19



US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:23:19

US3592111

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

Form: Unblinding

Generated On: 10 Jun 2021 08:19:37

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User entered empty.	System	18 Jan 2021 22:23:19

**US3592111**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:19:37**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User entered empty.	System	18 Jan 2021 22:23:19

US3592111

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 22:23:44

US3592111

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:37:42
User entered '18 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 22:23:44

US3592111

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4) (b) (4)	28 Apr 2021 07:23:47
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 19:04:22
User entered '08:55' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:04:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 21:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:37:42
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Jan 2021 22:23:44
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 22:23:44

US3592111

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User entered '18 Jan 2021 08:55'	System	22 Mar 2021 19:04:22
User entered empty.	System	18 Jan 2021 22:23:44

US3592111

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:19:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:38:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 22:24:03



US3592111

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:19:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:38:00
User entered '18 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 22:24:03

US3592111

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:19:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '08:48' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:04:37
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	22 Mar 2021 19:04:32
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	22 Mar 2021 19:04:32
User entered '08:45' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:04:32
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 21:38:02
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:38:00
Amendment Manager: User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:44:33
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 22:24:03

**US3592111**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:30:18
User entered '18 Jan 2021 08:48'	System	22 Mar 2021 19:04:37
User entered '18 Jan 2021 08:45'	System	22 Mar 2021 19:04:32
User entered empty.	System	18 Jan 2021 22:24:03

US3592111

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:19:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 20:16:30
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 14:18:16

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:30
User entered 'USA-US103-2020-mRNA-1273-P301000005'	System	10 Nov 2020 17:22:23
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 17:22:23

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastrointestinal ulcers and perforation, site unspecified, PT: Diverticular perforation, LLT: Diverticular perforation - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 05:50:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 05:50:27
Data point term sent to Coder	System	09 Nov 2020 20:19:33
User entered 'perforated diverticulitis'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 05:09:58
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'corrected' (Site from DM).	Diandra Henriques (b) (4)	18 Dec 2020 19:28:08
DataPoint Un-verified.	Diandra Henriques (b) (4)	18 Dec 2020 19:27:55
User entered 'No (N)' reason for change: Data Entry Error	Diandra Henriques (b) (4)	18 Dec 2020 19:27:55
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 05:57:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22



US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '03 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:19:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:02:05
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)	21 Jan 2021 16:32:13
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 'Not yet resolved' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 23:37:05
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)	19 Nov 2020 20:13:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:19:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:19:22



US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
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)	11 Nov 2020 06:21:46
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 'confirm correct subject has not be discharged. ' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 20:20:39
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Nov 2020 20:19:22
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '05 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 13:50:35
Query 'PV Query: Please provide the hospital discharge date when available. Please leave query open until information is available.' answered with 'discharge date added' (Site from Safety).	Diandra Henriques (b) (4)	25 Mar 2021 14:39:40
DataPoint Un-verified.	(b) (4)	
User entered '15 Nov 2020' reason for change: Data Entry Error	Diandra Henriques (b) (4)	25 Mar 2021 14:39:27
User opened query 'PV Query: Please provide the hospital discharge date when available. Please leave query open until information is available.' (Site from Safety).	(b) (4)	
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:01:32
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Not yet available' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:32:15
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 23:39:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:12:48
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22



US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 20:37:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 20:37:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 20:37:34
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 20:19:22
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22



US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
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)	21 Jan 2021 16:19:53
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 'data updated' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 23:40:07
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 05:57:29
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:13:42
	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send medical records from infectious disease specialist's office dated 10 Dec 2020, when available.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 20:11:41
User opened query 'PV Query: Please send medical records from surgeon's office dated 18 No2020, when available.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 20:11:36
User closed query 'Per DM CLR: Narrative indicates that the subject had CT Scan and 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)	30 Mar 2021 07:57:20
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)	26 Mar 2021 13:51:03
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 13:50:58
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)	26 Mar 2021 13:50:46

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'CRC WAS NOTIFIED OF SUBJECTS HOSPITALIZATION UPON RECEIVE MESSAGE FROM THE WEEKEND. TC TO SUBJECT MADE AT 0805 AND 0840 TO OBTAIN MORE INFORMATION. SUBJECT IS CURRENTLY HOSPITALIZED AT ST FRANCIS HOSPITAL. PER SUBJECT REPORT SHE WAS EXPERIENCING ABDOMINAL PAIN ON 03NOV2020 AND PRESENTED TO ER AT APPROXIMATELY 0330. DURING THAT VISIT A CT SCAN WAS PERFORMED AND SUBJECT WAS TOLD SHE HAD DIVERTICULITIS WITH PERFORATION. SHE WAS GIVEN MORPHINE AND DILAUDID FOR PAIN CONTROL IN THE ER. SUBJECT STATED THAT THEY SENT HER HOME FROM ER ABOUT 2 HOURS LATER WITH AUGMENTIN AND HYDROCODONE AND INSTRUCTIONS TO FOLLOW UP WITH PCP. SUBJECT WAS NOT ABLE TO GET INTO HER PCPS OFFICE FOR A FOLLOW APPT UNTIL AFTERNOON ON THURSDAY 05NOV2020. DURING THAT VISIT SUBJECT PCP FELT IT NECESSARY TO DIRECTLY ADMIT SUBJECT TO THE HOSPITAL FOR FURTHER ASSESSMENTS AND TREATMENT. REPEAT CT SCAN DONE UPON ADMISSION ALSO IDENTIFIED AN ABSCESS IN THE BOWEL. SUBJECT CONTINUES TO BE ADMITTED TO HOSPITAL SHE IS ON A CLEAR LIQUID DIET AND RECEIVING MEDICATION FOR PAIN MANAGEMENT AND NAUSEA CONTROL. PER SUBJECT THE CURRENT PLAN IS TO MONITOR FOR IMPROVEMENTS/DECLINE WHILE SHE RECEIVES IV ANTIBIOTICS AND IV FLUIDS,. NO SURGERY HAS BEEN DONE AND THERE ARE NO PLANS FOR SURGERY AT THIS TIME. WILL OBTAIN MEDICAL RECORDS FOR MORE PRECISE INFORMATION. ADDITIONAL DURING TC SUBJECT CONFIRMED THAT SHE HAS NO KNOWN HISTORY OF	(b) (4), (b) (6)	25 Mar 2021 19:36:38

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
DIVERTICULITIS OR ANY OTHER GI CONDITION PRIOR TO THIS.  Drain was placed on 10Nov2020 due to increased size of abscess and discontinued on 12Nov2020. Subject discharged to home on 15Nov2020. Per subject was seen in surgeon's office on 18Nov2020 and referred to Infectious disease specialist and was seen 10Dec2020. Medical records requested from both of these providers however none received at this time. Site will request again.' reason for change: Data Entry Error		
Query 'Per DM CLR: Narrative indicates that the subject had CT Scan and 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 'Medications and Dx Procedures from hospitalization have been added.' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:59:30
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'SENT VIA EMAIL 26 MAR 2021' (Site from Safety).	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 14:52:49
DataPoint Un-verified.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 14:52:28

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'CRC WAS NOTIFIED OF SUBJECTS HOSPITALIZATION UPON RECEIVE MESSAGE FROM THE WEEKEND. TC TO SUBJECT MADE AT 0805 AND 0840 TO OBTAIN MORE INFORMATION. SUBJECT IS CURRENTLY HOSPITALIZED AT ST FRANCIS HOSPITAL. PER SUBJECT REPORT SHE WAS EXPERIENCING ABDOMINAL PAIN ON 03NOV2020 AND PRESENTED TO ER AT APPROXIMATELY 0330. DURING THAT VISIT A CT SCAN WAS PERFORMED AND SUBJECT WAS TOLD SHE HAD DIVERTICULITIS WITH PERFORATION. SHE WAS GIVEN MORPHINE AND DILAUDID FOR PAIN CONTROL IN THE ER. SUBJECT STATED THAT THEY SENT HER HOME FROM ER ABOUT 2 HOURS LATER WITH AUGMENTIN AND HYDROCODONE AND INSTRUCTIONS TO FOLLOW UP WITH PCP. SUBJECT WAS NOT ABLE TO GET INTO HER PCPS OFFICE FOR A FOLLOW APPT UNTIL AFTERNOON ON THURSDAY 05NOV2020. DURING THAT VISIT SUBJECT PCP FELT IT NECESSARY TO DIRECTLY ADMIT SUBJECT TO THE HOSPITAL FOR FURTHER ASSESSMENTS AND TREATMENT. REPEAT CT SCAN DONE UPON ADMISSION ALSO IDENTIFIED AN ABSCESS IN THE BOWEL. SUBJECT CONTINUES TO BE ADMITTED TO HOSPITAL SHE IS ON A CLEAR LIQUID DIET AND RECEIVING MEDICATION FOR PAIN MANAGEMENT AND NAUSEA CONTROL. PER SUBJECT THE CURRENT PLAN IS TO MONITOR FOR IMPROVEMENTS/DECLINE WHILE SHE RECEIVES IV ANTIBIOTICS AND IV FLUIDS,. NO SURGERY HAS BEEN DONE AND THERE ARE NO PLANS FOR SURGERY AT THIS TIME. WILL OBTAIN MEDICAL RECORDS FOR MORE PRECISE INFORMATION. ADDITIONAL DURING TC SUBJECT CONFIRMED THAT SHE HAS NO KNOWN HISTORY OF	Diandra Henriques (b) (4)	25 Mar 2021 14:52:28



US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
DIVERTICULITIS OR ANY OTHER GI CONDITION PRIOR TO THIS.  ' reason for change: Data Entry Error		
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'No relevant medical history or pre-disposing risk factors identified. Subject had no history or diverticulitis, GI conditions, and per hospital report, was up to date on screening colonoscopies.' (Site from Safety).	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 14:41:22
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 COVID-19 test completed per hospital records.' (Site from Safety).	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 14:40:07
User opened query 'Per DM CLR: Narrative indicates that the subject had CT Scan and 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 05:57:42
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)	19 Nov 2020 20:13:28
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:12:59
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)	19 Nov 2020 20:12:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 20:37:14

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1780 of 2527

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 20:37:14
User entered 'CRC was notified of subjects hospitalization upon receive message from the weekend. TC to subject made at 0805 and 0840 to obtain more information. Subject is currently hospitalized at St Francis hospital. per subject report she was experiencing abdominal pain on 03NOV2020 and presented to ER at approximately 0330. During that visit a CT scan was performed and subject was told she had diverticulitis with perforation. She was given Morphine and dilaudid for pain control in the ER. Subject stated that they sent her home from ER about 2 hours later with Augmentin and hydrocodone and instructions to follow up with PCP. Subject was not able to get into her PCPS office for a follow appt until afternoon on Thursday 05nov2020. During that visit subject pcp felt it necessary to directly admit subject to the hospital for further assessments and treatment. REPEAT ct SCAN DONE upon admission also identified an abscess in the bowel. Subject continues to be admitted to hospital she is on a clear liquid diet and receiving medication for pain management and nausea control. Per subject the current plan is to monitor for improvements/decline while she receives IV antibiotics and IV fluids,. No surgery has been done and there are no plans for surgery at this time. Will obtain medical records for more precise information. Additional during TC subject confirmed that she has no known history of diverticulitis or any other GI condition prior to this.' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 20:37:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 20:19:22
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:19:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:19:22

**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:19:22

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Colonic abscess, LLT: Colonic abscess - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 23:52:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 23:52:43
Data point term sent to Coder	System	09 Nov 2020 20:39:07
User entered 'colon abscess'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38



US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '05 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:19:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:19:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 20:38:38



**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:19:37**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38



US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38



US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
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)	21 Jan 2021 16:20:27
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 'data updated' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 23:39:36
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 05:57:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:08:15
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:19:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 20:38:38

**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:19:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 20:38:38

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41



US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
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)	25 Mar 2021 15:02:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 15:02:06
Data point term sent to Coder	System	25 Mar 2021 15:00:14
User entered 'ABDOMINAL PAIN'	Diandra Henriques (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '03 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	System	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04



US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '30 Jan 2021'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	System	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Diandra Henriques (b) (4)	25 Mar 2021 16:27:48
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Diandra Henriques (b) (4)	25 Mar 2021 15:00:04
	(b) (4)	

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04



US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04



US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'Not Applicable (NOT APPLICABLE)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'l'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'I'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:00:04



US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered '0'	System	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41
User entered 'I'	System	25 Mar 2021 15:00:04

US3592111

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:41

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:45:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:45:28
Data point term sent to Coder	System	25 Mar 2021 16:29:41
User entered 'CONSTIPATION'	Diandra Henriques (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43



US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '03 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	System	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '03 Dec 2020'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	System	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43



US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43



US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'Not Applicable (NOT APPLICABLE)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'l'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43



US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered '0'	System	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43
User entered 'l'	System	25 Mar 2021 16:28:43

US3592111

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:31:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16



US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Candida infections, PT: Oral candidiasis, LLT: Oral candidiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:08:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:08:36
Data point term sent to Coder	System	25 Mar 2021 16:30:41
User entered 'ORAL CANDIDIASIS SECONDARY TO IV ANTIBIOTIC USE'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '18 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	System	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43



US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '25 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	System	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43



US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43



US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'Not Applicable (NOT APPLICABLE)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'l'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:29:43



US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered '0'	System	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16
User entered 'I'	System	25 Mar 2021 16:29:43

US3592111

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:16

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:32:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:32:41
Data point term sent to Coder	System	25 Mar 2021 16:31:43
User entered 'NAUSEA'	Diandra Henriques (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49



US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '05 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	System	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'No (N)' reason for change: Data Entry Error	Diandra Henriques (b) (4)	25 Mar 2021 16:33:58
User entered 'Yes (Y)'	Diandra Henriques (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '30 Nov 2020' reason for change: Data Entry Error	Diandra Henriques (b) (4)	25 Mar 2021 16:33:58
User entered empty.	(b) (4)	
	Diandra Henriques (b) (4)	25 Mar 2021 16:30:49
	(b) (4)	

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	System	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49



US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49



US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'Not Applicable (NOT APPLICABLE)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'l'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49



US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 16:33:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 16:33:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:58
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 16:30:49
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered '0'	System	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20
User entered 'I'	System	25 Mar 2021 16:30:49

US3592111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:34:20

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:33:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:33:29
Data point term sent to Coder	System	25 Mar 2021 16:32:44
User entered 'CHOLELITHIASIS'	Diandra Henriques (b) (4)	25 Mar 2021 16:32:04



US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:19:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:01:02
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Not resolved' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	20 Apr 2021 19:20:41
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 04:29:00
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04



US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04



US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04



US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Diandra Henriques (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

None

Audit	User	Time (GMT)
User entered 'l'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 21:28:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 21:28:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 21:28:27
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 16:32:04
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SEEN ON CT ABD/PELVIS DURING HOSPITALIZATION FOR SAE'	Diandra Henriques (b) (4)	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:19:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 16:32:04



**US3592111**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 16:32:04

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Bilateral pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:34:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 16:34:28
Data point term sent to Coder	System	25 Mar 2021 16:33:46
User entered 'BILATERAL PLEURAL EFFUSIONS'	Diandra Henriques (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:33:32



US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 06:17:13
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'confirm ongoing ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 21:30:04
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 04:29:07
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32



US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32



US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Diandra Henriques (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

None

Audit	User	Time (GMT)
User entered 'l'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 21:29:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 21:29:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 21:29:35
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 16:33:32
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 16:33:32



US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SEEN ON CT ABD/PELVIS DURING HOSPITALIZATION FOR SAE'	Diandra Henriques (b) (4)	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 16:33:32

US3592111

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:19:37

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 16:33:32

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:19:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:39
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 09:07:35
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'ADDED TO MED HISTORY' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	20 Apr 2021 19:27:09
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:59:40
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:42:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:42:46

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: TELMISARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:45:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:45:24
Data point term sent to Coder	System	19 Aug 2020 18:44:33
User entered 'telmisartan'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'hypertension'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '40'	(b) (4), (b) (6)	19 Aug 2020 18:43:57



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:22:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'entry is correct' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:44:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:43:57
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:43:57



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 18:43:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:43:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:47:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:47:48
Data point term sent to Coder	System	19 Aug 2020 18:46:36
User entered 'levothyroxine'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '50'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'ug (ug)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:45:56



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:22:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 18:46:33
answered with 'entry is correct' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:45:56
User entered 'un UNK 2014'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a solicited event per protocol and it started prior ICF. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 07:33:27
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a solicited event per protocol and it started prior ICF. Review and update entry as appropriate.' answered with 'corrected to yes' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 21:05:06
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	07 Oct 2020 21:04:57
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a solicited event per protocol and it started prior ICF. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:38:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:45:56

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 18:45:56

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 18:45:56

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:45:56



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:49:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:49:23
Data point term sent to Coder	System	19 Aug 2020 18:48:42
User entered 'liothyronine'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '7.5'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'ug (ug)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:48:34



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:23:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'entry is correct' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:48:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:48:34
User entered '1 May 2020'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:48:34

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 18:48:34



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 18:48:34

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:48:34

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
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)	19 Aug 2020 18:51:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:51:29
Data point term sent to Coder	System	19 Aug 2020 18:50:47
User entered 'multivitamin'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:50:24



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:24:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'entry is correct' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:50:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:50:24
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:50:24



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 18:50:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:50:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:53:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:53:19
Data point term sent to Coder	System	19 Aug 2020 18:52:51
User entered 'calcium'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '600'	(b) (4), (b) (6)	19 Aug 2020 18:52:01



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:25:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'entry is correct' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:52:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:52:01
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:52:01



**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:52:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 18:52:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 18:52:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:52:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:58:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:58:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:56:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:56:24
Data point term sent to Coder	System	19 Aug 2020 18:54:56
User entered 'vitamin d'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '400'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'IU (IU)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:54:15



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:25:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'entry is correct' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:54:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:54:15
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 18:54:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:54:15



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Mar 2021 11:03:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 11:03:42
Data point term sent to Coder	System	25 Mar 2021 15:11:26
Coding entries removed.	Diandra Henriques (b) (4)	25 Mar 2021 15:10:41
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 01:34:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 01:34:45
Data point term sent to Coder	System	19 Aug 2020 18:55:58
User entered 'phenylephrine'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
DataPoint Un-verified.	Diandra Henriques (b) (4)	25 Mar 2021 15:10:41
	(b) (4)	
User entered 'CHRONIC COUGH SECONDARY TO POST NASAL DRAINAGE' reason for change:	Diandra Henriques (b) (4)	25 Mar 2021 15:10:41
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:42:57
	(b) (4), (b) (6)	
User entered 'chronic cough'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '10'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:44



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 09:25:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'entry is correct' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:55:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:55:44
User entered 'un UNK 2011'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 18:55:44

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 18:55:44



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 18:55:44

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:55:44

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
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)	30 Mar 2021 14:03:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:23
Data point term sent to Coder Coding entries removed.	System Diandra Henriques (b) (4)	25 Mar 2021 15:10:24 25 Mar 2021 15:10:18
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
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.	Coder Import (b) (4)	01 Oct 2020 06:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 06:24:43
Data point term sent to Coder User entered 'fexofenadine'	System (b) (4), (b) (6)	30 Sep 2020 21:22:56 30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 11:28:27
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'UPDATED TO MATCH MED HX TERM' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:10:26
User entered 'CHRONIC COUGH SECONDARY TO POST NASAL DRAINAGE' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:10:18
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 21:43:00
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:42:57
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:27:45
User entered 'chronic cough'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '180'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:29



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'un UNK 2011'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:29



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:22:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 21:22:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 21:22:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 21:22:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
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)	30 Sep 2020 21:24:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 21:24:47
Data point term sent to Coder	System	30 Sep 2020 21:23:57
User entered 'influenza vaccine'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '0.5'	(b) (4), (b) (6)	30 Sep 2020 21:23:24



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'mL (mL)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '26 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:23:24



**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '26 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:23:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 21:23:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
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)	29 Mar 2021 05:53:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 05:53:58
Data point term sent to Coder	System	22 Mar 2021 18:41:27
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 18:40:59
Coding entries removed.	(b) (4), (b) (6)	22 Mar 2021 18:40:59
User entered 'AUGMENTIN (amoxicillin / clavulanate)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 18:40:59
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:42:57
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 SODIUM;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 00:18:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 00:18:10
Data point term sent to Coder	System	20 Jan 2021 23:40:03

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Augmentin'	(b) (4), (b) (6)	20 Jan 2021 23:39:28



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 07:23:10
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	22 Mar 2021 18:41:18
' answered with 'changed to no ' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 18:40:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 18:40:59
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:09:13
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Colon Abscess'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 875/125). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 07:24:43
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 875/125).	(b) (4), (b) (6)	22 Mar 2021 18:41:03
' answered with 'UPDATED ' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	22 Mar 2021 18:40:59
User entered '875/125' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 18:40:59
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 875/125). ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:08:31
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '875'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Jan 2021 23:39:28



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '18 Nov 2020'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered '23 Nov 2020'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User entered '2'	System	20 Jan 2021 23:39:28

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User entered '1'	System	20 Jan 2021 23:39:28



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:50
User entered '804 (804)'	System	20 Jan 2021 23:39:28

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
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.	(b) (4) Coder Import (b) (4)	25 Mar 2021 15:31:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 15:31:27
Data point term sent to Coder	System	25 Mar 2021 15:30:59
User entered 'TYLENOL'	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'No (N)'	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'ABDOMINAL PAIN'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:30:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered '650'	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'mg (mg)'	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered empty.	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'as needed (PRN)'	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered empty.	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Oral (ORAL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:30:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered empty.	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered '05 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered '0'	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 May 2021 06:16:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'confirm ongoing takes PRN' (Site from DM).	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 21:31:41
	(b) (4), (b) (6)	07 Apr 2021 04:57:40
	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered empty.	Diandra Henriques (b) (4)	25 Mar 2021 15:30:12
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:30:12



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:30:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:30:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:30:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Mar 2021 06:53:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:53:57
Data point term sent to Coder	System	25 Mar 2021 15:33:01
User entered 'OXYCODONE/ACETAMINOPHEN'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'ADBOMINAL PAIN'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '7.5/325'	Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'mg (mg)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'as needed (PRN)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Oral (ORAL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '15 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '22 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:32:58

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User entered empty.	System	25 Mar 2021 15:32:58

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User entered empty.	System	25 Mar 2021 15:32:58

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:07:12
User entered empty.	System	25 Mar 2021 15:32:58

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 15:34:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:34:28
Data point term sent to Coder	System	25 Mar 2021 15:34:02
User entered 'ONDANSETRON'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'NAUSEA'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '4'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'mg (mg)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'as needed (PRN)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Oral (ORAL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '05 Nov 2020'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '30 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:33:53

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User entered empty.	System	25 Mar 2021 15:33:53

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User entered empty.	System	25 Mar 2021 15:33:53

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:32
User entered empty.	System	25 Mar 2021 15:33:53

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	29 Mar 2021 06:51:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:51:05
Data point term sent to Coder	System	25 Mar 2021 15:37:12
User entered 'ONDANSETRON 2 MG/ML'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:36:24



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'NAUSEA'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '2'	Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'mL (mL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'as needed (PRN)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '05 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '15 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:36:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User entered empty.	System	25 Mar 2021 15:36:24

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User entered empty.	System	25 Mar 2021 15:36:24



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:59
User entered empty.	System	25 Mar 2021 15:36:24

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:30
Data point term sent to Coder	System	25 Mar 2021 15:42:19
User entered 'FLAGYL 5 MG/ML'	Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'PERFORATED DIVERTICULITIS'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '100'	Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'mL (mL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'twice daily (BID)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '05 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '15 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:42:12



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User entered '2'	System	25 Mar 2021 15:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User entered 'I'	System	25 Mar 2021 15:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:06:56
User entered '804 (804)'	System	25 Mar 2021 15:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 16:40:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 16:40:29
Data point term sent to Coder	System	25 Mar 2021 16:39:54
User entered 'BACTRIM DS'	Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'COLON ABSCESS'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '800/160'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'mg (mg)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'twice daily (BID)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4)	
	Diandra Henriques (b) (4)	25 Mar 2021 16:39:15
	(b) (4)	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Oral (ORAL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '15 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '18 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:39:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User entered '2'	System	25 Mar 2021 16:39:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User entered '1'	System	25 Mar 2021 16:39:15

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:50
User entered '804 (804)'	System	25 Mar 2021 16:39:15

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Apr 2021 11:05:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:05:16
Data point term sent to Coder	System	25 Mar 2021 15:44:25
User entered 'HYDROMORPHONE 1 MG/ML'	Diandra Henriques (b) (4) (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'ABDOMINAL PAIN'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0.5'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'mL (mL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'as needed (PRN)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '05 Nov 2020'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '15 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:44:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User entered empty.	System	25 Mar 2021 15:44:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User entered empty.	System	25 Mar 2021 15:44:01

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:58
User entered empty.	System	25 Mar 2021 15:44:01

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 15:48:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 15:48:27
Data point term sent to Coder	System	25 Mar 2021 15:47:29
User entered 'MIRALAX'	Diandra Henriques (b) (4)	25 Mar 2021 15:47:29



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'CONSTIPATION'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '17'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'g (g)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'once daily (QD)'	Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Oral (ORAL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:19:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '05 Nov 2020'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '15 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:47:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User entered 'I'	System	25 Mar 2021 15:47:29

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User entered '1'	System	25 Mar 2021 15:47:29



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:02
User entered '804 (804)'	System	25 Mar 2021 15:47:29

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 11:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 11:54:43
Data point term sent to Coder	System	25 Mar 2021 15:50:43
User entered 'ROCEPHIN'	Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'COLON ABSCESS'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'l'	Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'g (g)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'once daily (QD)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:19:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '05 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '15 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:50:25



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User entered 'I'	System	25 Mar 2021 15:50:25

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User entered '1'	System	25 Mar 2021 15:50:25

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:20
User entered '804 (804)'	System	25 Mar 2021 15:50:25

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: ROXICODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 15:53:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 15:53:28
Data point term sent to Coder	System	25 Mar 2021 15:52:47
User entered 'ROXICODONE'	Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'ABDOMINAL PAIN'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '5'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'mg (mg)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'as needed (PRN)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Oral (ORAL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '05 Nov 2020'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '15 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:52:19

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User entered empty.	System	25 Mar 2021 15:52:19

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User entered empty.	System	25 Mar 2021 15:52:19

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:08:44
User entered empty.	System	25 Mar 2021 15:52:19

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 09:57:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 09:57:36
Data point term sent to Coder	System	25 Mar 2021 16:42:56
User entered 'FLUCONAZOLE SWISH SOLUTION 10 MG/ML'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'ORAL CANDIDIASIS SECONDARY TO IV ANTIBIOTIC USE'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'l'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'mL (mL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'once daily (QD)'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Oral (ORAL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '19 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:12



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '25 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User entered 'I'	System	25 Mar 2021 16:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User entered '1'	System	25 Mar 2021 16:42:12

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:09
User entered '804 (804)'	System	25 Mar 2021 16:42:12

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:44:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:44:35
Data point term sent to Coder	System	25 Mar 2021 16:43:57
User entered 'PROBIOTICS'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'Yes (Y)'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'DIETARY SUPPLEMENT'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:42:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'I'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'capsule (CAPSULE)'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered empty.	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'once daily (QD)'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered empty.	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'Oral (ORAL)'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered empty.	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered '19 Nov 2020'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered '0'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'Yes (Y)'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered empty.	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
	(b) (4)	
User entered 'No (N)'	Diandra Henriques (b) (4)	25 Mar 2021 16:42:57
	(b) (4)	

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Mar 2021 16:42:57

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 16:42:57



**US3592111**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 16:42:57

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:44:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:44:36
Data point term sent to Coder	System	25 Mar 2021 16:43:57
User entered 'MAGNESIUM CITRATE'	Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'CONSTIPATION'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '10'	Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Other (OTHER)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'OUNCES'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'once (ONCE)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51



US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'Oral (ORAL)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:19:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '03 Dec 2020'	Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:19:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '0'	Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered '03 Dec 2020'	Diandra Henriques (b) (4)	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:19:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User signature succeeded.	Terry Poling (b) (4)	30 Apr 2021 15:49:08
User entered 'No (N)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:43:51



US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:19:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User entered empty.	System	25 Mar 2021 16:43:51

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User entered empty.	System	25 Mar 2021 16:43:51

US3592111

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:19:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:09:14
User entered empty.	System	25 Mar 2021 16:43:51

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:19:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:39
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:43:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 20:46:44
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 14:18:32

US3592111

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:19:37**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:48:05

US3592111

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'placement of wound drain'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:48:05

US3592111

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:48:05

US3592111

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:19:37**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:48:05



US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:19:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered '3 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:51:10

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:19:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'computed tomography scan'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:51:10

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:51:10

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:19:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:51:10

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:19:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:51:50

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:19:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'drain removal'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:51:50

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:51:50

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:19:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 20:51:50



US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:19:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered '03 Nov 2020'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 14:55:22

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:19:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'CT ABDOMEN AND PELVIS'	(b) (4)	
reason for change: Data Entry Error	Diandra Henriques (b) (4)	25 Mar 2021 15:01:07
User entered 'CT ABDOMEN'	(b) (4)	
	Diandra Henriques (b) (4)	25 Mar 2021 14:55:22
	(b) (4)	

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'Adverse Event (AE)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 14:55:22

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:19:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:14
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 14:55:22

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:19:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:17
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered '05 Nov 2020'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 14:58:34

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:19:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:17
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'CT ABDOMEN AND PELVIS'	(b) (4)	
reason for change: Data Entry Error	Diandra Henriques (b) (4)	25 Mar 2021 15:56:29
User entered 'CT ABDOMEN'	(b) (4)	
	Diandra Henriques (b) (4)	25 Mar 2021 14:58:34
	(b) (4)	

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:17
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'Adverse Event (AE)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 14:58:34

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:19:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:17
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 14:58:34



US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:19:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered '10 Nov 2020'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:01:44

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:19:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'CT GUIDED WOUND DRAIN PLACEMENT' reason for change: Data Entry Error	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:23:28
User entered 'CT GUIDED DRAIN PLACEMENT'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:01:44

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'Adverse Event (AE)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:01:44

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:19:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:21
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 16:01:44

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:19:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered '12 Nov 2020'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:03:00

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:19:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'CT ABDOMEN AND PELVIS'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:03:00

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:19:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered 'Adverse Event (AE)'	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:03:00

US3592111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:19:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:24:25
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:48:01
User entered empty.	(b) (4) Diandra Henriques (b) (4)	25 Mar 2021 15:03:00



US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'USA-US103-2020-MRNA-1273-P301000005'	System	10 Nov 2020 17:22:23

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23



US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Terry'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Poling'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '1709 S Rock Rd'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Wichita'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'KS'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '67207'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
User entered 'US'	System	10 Nov 2020 17:23:05

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Mar 2021 13:51:35
User entered '1'	System	10 Nov 2020 17:23:05



US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'USA-US103-2020-MRNA-1273-P301000005'	System	10 Nov 2020 17:22:23

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23



US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Terry'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Poling'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '1709 S Rock Rd'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Wichita'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'KS'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '67207'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
User entered 'US'	System	10 Nov 2020 17:23:05

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Mar 2021 13:51:35
User entered '1'	System	10 Nov 2020 17:23:05



**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:19:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
User entered '10/Nov/2020 17:23'	System	10 Nov 2020 17:23:05

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:19:37

**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 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 17:23:05

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'USA-US103-2020-MRNA-1273-P301000005'	System	10 Nov 2020 17:22:23

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

Death

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'Yes (Y)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23



US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 17:22:55
User entered 'No (N)'	System	10 Nov 2020 17:22:23

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Terry'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Poling'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '1709 S Rock Rd'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'Wichita'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered 'KS'	(b) (4) System	26 Mar 2021 13:51:35

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '67207'	(b) (4) System	26 Mar 2021 13:51:35



US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:19:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	11 Nov 2020 21:07:21
User entered 'US'	System	10 Nov 2020 17:23:05

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:19:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Mar 2021 13:51:35
User entered '1'	System	10 Nov 2020 17:23:05

**US3592111**

**Folder: SAE USA-US103-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:19:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:23:47
User entered '26/Mar/2021 09:51'	(b) (4) System	26 Mar 2021 13:51:35

US3592111

Folder: SAE USA-US103-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:19:37

**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 07:23:47
User entered 'I'	(b) (4) (D) (4), (D) (6)	26 Mar 2021 13:51:35